

US3302212 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:58:18

All time stamps listed in this document are displayed in GMT

US3302212

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 18:55:26

Generated On: 09 Jun 2021 16:58:18

[Participant ID](#)

US3302212

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

US3302212

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 18:55:27

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Date of Birth (MMM yyyy)	(b) (6) 1986
Age	34
Age Units	YEARS
Age (Derived)	34
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 18:55:27

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 18:55:27

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 18:55:27

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 18:55:27

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Condition	CERVICAL STENOSIS
Start date (dd MMM yyyy)	05 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 18:55:27

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:55:27

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:01 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:01
Height (<i>xxx.x</i>)	72 in
Weight (<i>xxx.x</i>)	205 lb
BMI (<i>xxx.x</i>)	27.86113 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:55:27

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:55:27

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 18:55:28

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

What was the participant's randomization number? 104341

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 18:55:28

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	11:01 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:01
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:32
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:55:27

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Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:02 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 12:02

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	11:28 (24 HR)
Collection date and time (derived)	14 AUG 2020 11:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:26	14 AUG 2020 11:26
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

14 AUG 2020 12:22

PC Open Date & Time

14 AUG 2020 12:22

PC Close Date & Time

14 AUG 2020 14:52

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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	15 AUG 2020 08:46
PC Open Date & Time	14 AUG 2020 15:47
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

98.1 °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

15 AUG 2020 22:46

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

98.5 °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

16 AUG 2020 20:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

17 AUG 2020 16:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 14:47

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

19 AUG 2020 12:22

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 12:33

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:23

PC Open Date & Time

14 AUG 2020 12:22

PC Close Date & Time

14 AUG 2020 14:52

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 08:46

PC Open Date & Time

14 AUG 2020 15:47

PC Close Date & Time

15 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 22:46

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 20:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 16:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 14:48

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 12:22

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 12:34

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 12:23
PC Open Date & Time	14 AUG 2020 12:22
PC Close Date & Time	14 AUG 2020 14:52

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 08:47
PC Open Date & Time	14 AUG 2020 15:47
PC Close Date & Time	15 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 22:47
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

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 ☒

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:44
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

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 ☒

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 16:26
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 14:48
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2134

EAB) (1725)

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2134

EAB) (1725)

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:34
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3302212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	08:36 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 08:36
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	09:26 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:26
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3302212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 8:56 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 8:56

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

US3302212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

08:45 (24 HR)

Collection date and time (derived)

11 SEP 2020 08:45

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:43	11 SEP 2020 08:43
Nasopharyngeal Swab 2	Yes	08:43	11 SEP 2020 08:43

US3302212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 09:16

PC Open Date & Time

11 SEP 2020 09:16

PC Close Date & Time

11 SEP 2020 11:46

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:41

PC Close Date & Time

12 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

12 SEP 2020 14:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

98.4 °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

13 SEP 2020 13:48

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

14 SEP 2020 15:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 12:32

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 09:16

PC Open Date & Time

11 SEP 2020 09:16

PC Close Date & Time

11 SEP 2020 11:46

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:41

PC Close Date & Time

12 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

12 SEP 2020 14:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

13 SEP 2020 13:48

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

14 SEP 2020 15:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

15 SEP 2020 12:32

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

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 ☐

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

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 09:17
PC Open Date & Time	11 SEP 2020 09:16
PC Close Date & Time	11 SEP 2020 11:46

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:41

PC Close Date & Time

12 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

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 ☒

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 14:09
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

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 ☒

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:48
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

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 ☒

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 16:02
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

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 ☒

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 12:32
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

Yes ☐

PC Time stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3302212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

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

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:55:39

Generated On: 09 Jun 2021 16:58:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:55:39

Generated On: 09 Jun 2021 16:58:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:51 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 08:51
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	94 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:55:39

Generated On: 09 Jun 2021 16:58:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3302212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 OCT 2020

Collection time (00:00-23:59)

08:53 (24 HR)

Collection date and time (derived)

06 OCT 2020 08:53

US3302212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:28

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 OCT 2020 08:42:45
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

21 OCT 2020 00:01:38

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 09:36:46

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 NOV 2020 08:04:05
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 15:39:03

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 09:56:13
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 14:38:43

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 10:10:47
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 15:06:18

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 11:01:48

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 00:02:38

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 17:37:04

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 09:14:09
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 09:03:17
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 00:12:17

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 07:55:57
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 12:01:50

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 00:01:39
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 00:01:51

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 09:59:38

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 14:36:15

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 01:26:59

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 09:48:32

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 09:47:30
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 10:42:10

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 APR 2021 19:36:05
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:16:22

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission

03 MAY 2021 11:31:13

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 306

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

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

No ☐
Yes ☐

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Patient Cloud Open Date & Time	26 DEC 2021 00:01
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Patient Cloud Close Date & Time	30 DEC 2021 23:59
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US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Patient Cloud Open Date & Time	24 JUL 2022 00:01
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Patient Cloud Close Date & Time	28 JUL 2022 23:59
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US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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°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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3302212

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:58:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 00:02:01

US3302212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

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

Visit date (dd MMM yyyy)	16 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 15:55:28

Generated On: 09 Jun 2021 16:58:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 MAR 2021
Time of assessment (00:00-23:59)	13:42 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 13:42
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302212

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

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.

US3302212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 MAR 2021

Collection time (00:00-23:59)

13:45 (24 HR)

Collection date and time (derived)

16 MAR 2021 13:45

US3302212

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302212

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3302212

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:58:18

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3302212

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

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

Visit date (dd MMM yyyy)	16 FEB 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3302212

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

Form: Unblinding

Data signed: (b) (4) 20 Apr 2021 17:54:12

Generated On: 09 Jun 2021 16:58:18

Date of updated informed consent (*dd MMM yyyy*) 16 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 16 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3302212

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

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

Collection date (dd MMM yyyy)	16 FEB 2021
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Collection time (00:00-23:59)	13:49 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	16 FEB 2021 13:49
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US3302212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

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

Collection date (dd MMM yyyy)	16 FEB 2021
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Collection time (00:00 - 23:59)	13:47
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Collection Date and Time (derived)	16 FEB 2021 13:47
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US3302212

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 18:55:26

Generated On: 09 Jun 2021 16:58:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 21:41:55

Generated On: 09 Jun 2021 16:58:18

AEID	USA-US087-2020-MRNA-1273-P30 1000002
Adverse event	WORSENING CERVICAL RADICULOPATHY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 21:41:55

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 21:41:55

Generated On: 09 Jun 2021 16:58:18

PT CAME IN FOR VISIT 3 AND
REPORTED THAT HE HAD A
CERVICAL FUSION TO REPAIR
A HERNIATED DISC ON
28SEP2020 AND WAS ADMITTED
AND DISCHARGED ON
30SEP2020 ALL AE'S WERE
UPDATED AND SAE WAS
REPORTED. CONMEDS WERE
UPDATED AND MEDICAL
RECORDS WERE REQUESTED.
FINAL FOLLOW UP WILL BE
COMPLETED ONCE RECORDS
ARE RECEIVED. RECORDS
WERE RECEIVED AND
UPDATES MADE TO SOURCE
AND EDC

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

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

Yes ☒

No ☐

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING CERVICAL
RADICULOPATHY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 8

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication EPHEDRINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication GLYCOPYRROLATE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 0.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 0.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication KETAMINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication LIDOCAINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 230

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication ROCURONIUM

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication SUCCINYLCHOLINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication REMIFENTANIL

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 1.95

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

Dose per administration 4280

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE
ANESTHESIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

Name of Medication LACTADED RINGERS INFUSION
PREMIX

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PREP

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 12:44:22

Generated On: 09 Jun 2021 16:58:18

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 18:55:27

Generated On: 09 Jun 2021 16:58:18

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 SEP 2020	CERVICAL FUSION	Adverse Event	

US3302212

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:58:18

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

US3302212

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:58:18

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 ☐

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

SAEID	USA-US087-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

SAEID	USA-US087-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/OCT/2020 07:57
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

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

SAEID	USA-US087-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/NOV/2020 19:39
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

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

SAEID	USA-US087-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/NOV/2020 00:55
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

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

SAEID	USA-US087-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/NOV/2020 20:54
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

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

SAEID	USA-US087-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/NOV/2020 22:05
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

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

SAEID	USA-US087-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/JAN/2021 10:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 25 Mar 2021 18:07:19

Generated On: 09 Jun 2021 16:58:18

SAEID	USA-US087-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/MAR/2021 10:44
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

Audit

US3302212 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

US3302212

Form: Participant Creation

Generated On: 09 Jun 2021 16:58:18

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'US3302212'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:59:50

US3302212

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	brittany cooksey (b) (4)	14 Aug 2020 15:44:12

US3302212

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:59:51

US3302212

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Clinic (Clinic)'	brittany cooksey (b) (4)	14 Aug 2020 15:44:12

US3302212

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'SCRN'	System	14 Aug 2020 15:44:12

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered (b) (6) 1986'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:59:52

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '34'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'YEARS'	System	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered '34'	System	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Male (M)'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'I'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:58:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '14 Aug 2020'	brittany cooksey (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'Aug 2020'	System	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered '2020'	System	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Amendment 2 (2)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	brittany cooksey (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	brittany cooksey (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:59:51

US3302212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:58:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'I'	System	14 Aug 2020 15:45:13

US3302212

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:13

US3302212

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:58:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:28:14
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 22:13:24
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 22:09:30
User entered 'No (N)'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:01

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 13:30:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 13:30:44
Data point term sent to Coder	System	13 Nov 2020 13:29:45
User entered 'Degenerative Disc Disease'	(b) (4), (b) (6)	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:25
User entered 'un Apr 2020'	(b) (4), (b) (6)	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:27
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:30
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:32
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'Apr 2020'	System	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered '2020'	System	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered empty.	System	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered empty.	System	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:15:46
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: Cervical spinal stenosis, LLT: Cervical spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 13:30:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 13:30:44
Data point term sent to Coder	System	13 Nov 2020 13:29:45
User entered 'Cervical Stenosis'	(b) (4), (b) (6)	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:48
User entered '05 Aug 2020'	(b) (4), (b) (6)	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:50
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:15:58
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:16:00
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'Aug 2020'	System	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered '2020'	System	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered empty.	System	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered empty.	System	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:19:01
Query 'Please review source and revise if needed. Source states worsening cervical radiculopathy.' canceled (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:18:56
User opened query 'Please review source and revise if needed. Source states worsening cervical radiculopathy.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:18:04
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 13:30:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 13:30:45
Data point term sent to Coder	System	13 Nov 2020 13:29:45
User entered 'Cervical Radiculopathy'	(b) (4), (b) (6)	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:19:03
Query 'Please review source and revise if needed. Source states start date as 05Aug2020..' canceled (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:18:55
User opened query 'Please review source and revise if needed. Source states start date as 05Aug2020..' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:18:32
User entered 'un Apr 2020'	(b) (4), (b) (6)	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:18:34
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:18:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:18:38
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:18:41
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'Apr 2020'	System	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered '2020'	System	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered empty.	System	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered empty.	System	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '14 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11:01'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered '14 Aug 2020 11:01'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '72' in	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:11:36
DataPoint set to visible.	System	14 Aug 2020 15:45:13

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '205' lb	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:11:36
DataPoint set to visible.	System	14 Aug 2020 15:45:13

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
Amendment Manager: User entered '27.86113'	System	16 Sep 2020 23:57:04
User entered '27.9'	System	17 Aug 2020 23:11:36
DataPoint set to visible.	System	14 Aug 2020 15:45:13

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'kg/m2'	System	17 Aug 2020 23:11:36
DataPoint set to visible.	System	14 Aug 2020 15:45:13

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 07:05:02
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	Brittany Belcher (b) (4)	08 Oct 2020 13:22:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	06 Oct 2020 17:05:53
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:27:57
User entered '98.7' F	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:53
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:53
User entered '77'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'bpm'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:53
User entered '16'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'breaths/min'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:53
User entered '140'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'mmHg'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:53
User entered '86'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User entered 'mmHg'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24

US3302212

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:11:42

US3302212

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 16:17:28
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 12:58:19
User entered '14 Aug 2020'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:42

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	03 Nov 2020 18:22:42
User entered '1'	(b) (4) brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '1' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	03 Nov 2020 18:22:42
User entered '0'	(b) (4) brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:58:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:13:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	brittany cooksey (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	brittany cooksey (b) (4)	14 Aug 2020 15:46:05

US3302212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '14 Aug 2020'	(b) (4) brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:05

US3302212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Clinic (Clinic)'	brittany cooksey (b) (4)	14 Aug 2020 15:46:05

US3302212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'VISIT1'	System	14 Aug 2020 15:46:05

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:44:40

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:18

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:30:42
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:30:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 15:44:40
User entered '104341' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:44:40

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:44:40

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	(b) (4) brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:18

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	(b) (4) brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	brittany cooksey (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:58:18

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:04:45
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:16:21

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 05:55:23
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' answered with 'updated' (Site from DM).	Wendy Taylor (b) (4)	08 Oct 2020 14:55:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:27:40
User entered '72' in	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered '205' lb	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 05:55:23
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' answered with 'updated' (Site from DM).	Wendy Taylor (b) (4)	08 Oct 2020 14:55:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:27:40
User entered '72' in	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered '205' lb	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered 'No (N)'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 18:55:29
User entered '14 Aug 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered empty.	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11:01' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered empty.	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '14 Aug 2020 11:01'	System	06 Oct 2020 17:05:29
User entered empty.	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '98.7' F reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered empty.	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered empty.	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '77' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered empty.	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'bpm'	System	06 Oct 2020 17:05:29
User entered empty.	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '16' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered empty.	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'breaths/min'	System	06 Oct 2020 17:05:29
User entered empty.	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '140' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered empty.	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	06 Oct 2020 17:05:29
User entered empty.	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '86' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered empty.	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	06 Oct 2020 17:05:29
User entered empty.	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 05:55:23
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' answered with 'updated' (Site from DM).	Wendy Taylor (b) (4)	08 Oct 2020 14:55:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 05:27:40
User entered '72' in	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:58:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 17:05:29
User entered '205' lb	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '14 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 04:30:36
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 23:12:45
User entered '12:32'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '14 Aug 2020 12:32'	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '98.4' F	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Oral (Oral)'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '70'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'bpm'	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '18'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'breaths/min'	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '118'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '76'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:12:51

US3302212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4)	17 Aug 2020 23:12:51

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) brittany cooksey (b) (4) (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4) brittany cooksey (b) (4) (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	brittany cooksey (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '14 Aug 2020'	brittany cooksey (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '12:02'	(b) (4) brittany cooksey (b) (4) (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '14 Aug 2020 12:02'	System	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Left Arm (LEFT ARM)'	brittany cooksey (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'ONCE'	System	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:13:18

US3302212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '14 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:13:18

US3302212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11:28'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:13:18

US3302212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '14 Aug 2020 11:28'	System	17 Aug 2020 23:13:18

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:58:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '14 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11:26'	(b) (4)	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '14 Aug 2020 11:26'	System	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	20 Oct 2020 21:19:07
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty; reason for change Data Entry Error	(b) (4) Brittany Belcher (b) (4)	20 Oct 2020 21:19:07
User entered '11:26'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered empty.	System	20 Oct 2020 21:19:07
User entered '14 Aug 2020 11:26'	System	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	17 Aug 2020 23:13:50

US3302212

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'I'	System	17 Aug 2020 23:13:50

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:22:16', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '49bbd3b2-7f0c-433a-9cb9-72a368ef3bbb'	System	14 Aug 2020 16:22:36
User entered 'Yes (Y)'	System	14 Aug 2020 16:22:36

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:22:21', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '49bbd3b2-7f0c-433a-9cb9-72a368ef3bbb'	System	14 Aug 2020 16:22:36
User entered '98.4'	System	14 Aug 2020 16:22:36

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:22:26', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '49bbd3b2-7f0c-433a-9cb9-72a368ef3bbb'	System	14 Aug 2020 16:22:36
User entered 'No (N)'	System	14 Aug 2020 16:22:36

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:22:33', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '49bbd3b2-7f0c-433a-9cb9-72a368ef3bbb'	System	14 Aug 2020 16:22:36
User entered '14 Aug 2020 12:22'	System	14 Aug 2020 16:22:36

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Aug 2020 12:22'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Aug 2020 14:52'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:45:44', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '54e604b9-3c33-4027-aacf-1d8f4dc123f7'	System	15 Aug 2020 12:46:04
User entered 'Yes (Y)'	System	15 Aug 2020 12:46:04

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:45:49', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '54e604b9-3c33-4027-aacf-1d8f4dc123f7'	System	15 Aug 2020 12:46:04
User entered '98.4'	System	15 Aug 2020 12:46:04

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:45:55', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '54e604b9-3c33-4027-aacf-1d8f4dc123f7'	System	15 Aug 2020 12:46:04
User entered 'No (N)'	System	15 Aug 2020 12:46:04

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:01', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '54e604b9-3c33-4027-aacf-1d8f4dc123f7'	System	15 Aug 2020 12:46:04
User entered '15 Aug 2020 08:46'	System	15 Aug 2020 12:46:04

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Aug 2020 15:47'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 2'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:45:51', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f5ced950-98c7-41d0-9631-e5e03d87d4f5'	System	16 Aug 2020 02:46:18
User entered 'Yes (Y)'	System	16 Aug 2020 02:46:18

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:46:06', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f5ced950-98c7-41d0-9631-e5e03d87d4f5'	System	16 Aug 2020 02:46:18
User entered '98.1'	System	16 Aug 2020 02:46:18

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:46:11', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f5ced950-98c7-41d0-9631-e5e03d87d4f5'	System	16 Aug 2020 02:46:18
User entered 'No (N)'	System	16 Aug 2020 02:46:18

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:46:14', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f5ced950-98c7-41d0-9631-e5e03d87d4f5'	System	16 Aug 2020 02:46:18
User entered '15 Aug 2020 22:46'	System	16 Aug 2020 02:46:18

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 3'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:42:41', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9e44cdde-7dfb-4095-b781-996f4d6f3c59'	System	17 Aug 2020 00:43:20
User entered 'Yes (Y)'	System	17 Aug 2020 00:43:20

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:42:45', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9e44cdde-7dfb-4095-b781-996f4d6f3c59'	System	17 Aug 2020 00:43:20
User entered '98.5'	System	17 Aug 2020 00:43:20

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:42:48', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9e44cdde-7dfb-4095-b781-996f4d6f3c59'	System	17 Aug 2020 00:43:20
User entered 'No (N)'	System	17 Aug 2020 00:43:20

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:18', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9e44cdde-7dfb-4095-b781-996f4d6f3c59'	System	17 Aug 2020 00:43:20
User entered '16 Aug 2020 20:43'	System	17 Aug 2020 00:43:20

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 4'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:25:27', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c19fb2bd-adf6-4949-99e4-42082eeca762'	System	17 Aug 2020 20:25:42
User entered 'Yes (Y)'	System	17 Aug 2020 20:25:42

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:25:32', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c19fb2bd-adf6-4949-99e4-42082eeca762'	System	17 Aug 2020 20:25:42
User entered '98.6'	System	17 Aug 2020 20:25:42

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:25:35', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c19fb2bd-adf6-4949-99e4-42082eeca762'	System	17 Aug 2020 20:25:42
User entered 'No (N)'	System	17 Aug 2020 20:25:42

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:25:40', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c19fb2bd-adf6-4949-99e4-42082eeca762'	System	17 Aug 2020 20:25:42
User entered '17 Aug 2020 16:25'	System	17 Aug 2020 20:25:42

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 5'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:47:37', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '2f401666-0353-458c-ac1a-65d5b2f77b1f'	System	18 Aug 2020 18:48:14
User entered 'Yes (Y)'	System	18 Aug 2020 18:48:14

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:47:42', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '2f401666-0353-458c-ac1a-65d5b2f77b1f' User entered '98.2'	System	18 Aug 2020 18:48:14
	System	18 Aug 2020 18:48:14

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:47:45', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '2f401666-0353-458c-ac1a-65d5b2f77b1f'	System	18 Aug 2020 18:48:14
User entered 'No (N)'	System	18 Aug 2020 18:48:14

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:47:49', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '2f401666-0353-458c-ac1a-65d5b2f77b1f'	System	18 Aug 2020 18:48:14
User entered '18 Aug 2020 14:47'	System	18 Aug 2020 18:48:14

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 6'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:02', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f7783c01-f0ef-4b67-8fb3-63c4115e9cec'	System	19 Aug 2020 16:22:19
User entered 'Yes (Y)'	System	19 Aug 2020 16:22:19

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:11', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f7783c01-f0ef-4b67-8fb3-63c4115e9cec'	System	19 Aug 2020 16:22:19
User entered '98.4'	System	19 Aug 2020 16:22:19

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:14', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f7783c01-f0ef-4b67-8fb3-63c4115e9cec'	System	19 Aug 2020 16:22:19
User entered 'No (N)'	System	19 Aug 2020 16:22:19

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:17', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f7783c01-f0ef-4b67-8fb3-63c4115e9cec'	System	19 Aug 2020 16:22:19
User entered '19 Aug 2020 12:22'	System	19 Aug 2020 16:22:19

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 7'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:33:43', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4c7e5208-8ef0-4e0f-8cb8-1fdd83e0d798'	System	20 Aug 2020 16:33:55
User entered 'Yes (Y)'	System	20 Aug 2020 16:33:55

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:33:47', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4c7e5208-8ef0-4e0f-8cb8-1fdd83e0d798'	System	20 Aug 2020 16:33:55
User entered '98.8'	System	20 Aug 2020 16:33:55

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:33:50', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4c7e5208-8ef0-4e0f-8cb8-1fdd83e0d798'	System	20 Aug 2020 16:33:55
User entered 'No (N)'	System	20 Aug 2020 16:33:55

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:33:53', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4c7e5208-8ef0-4e0f-8cb8-1fdd83e0d798'	System	20 Aug 2020 16:33:55
User entered '20 Aug 2020 12:33'	System	20 Aug 2020 16:33:55

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:22:44', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '09920caf-8256-4376-aaf8-2b3c8259f5af'	System	14 Aug 2020 16:23:54
User entered 'None (1)'	System	14 Aug 2020 16:23:54

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:22:52', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '09920caf-8256-4376-aaf8-2b3c8259f5af'	System	14 Aug 2020 16:23:54
User entered 'No (N)'	System	14 Aug 2020 16:23:54

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:01', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '09920caf-8256-4376-aaf8-2b3c8259f5af'	System	14 Aug 2020 16:23:54
User entered 'No (N)'	System	14 Aug 2020 16:23:54

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:08', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '09920caf-8256-4376-aaf8-2b3c8259f5af'	System	14 Aug 2020 16:23:54
User entered 'None (1)'	System	14 Aug 2020 16:23:54

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:13', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '09920caf-8256-4376-aaf8-2b3c8259f5af'	System	14 Aug 2020 16:23:54
User entered '14 Aug 2020 12:23'	System	14 Aug 2020 16:23:54

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Aug 2020 12:22'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Aug 2020 14:52'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:14', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4177f231-413d-47a5-86fd-99be57473a7b'	System	15 Aug 2020 12:46:33
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 12:46:33

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:17', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4177f231-413d-47a5-86fd-99be57473a7b'	System	15 Aug 2020 12:46:33
User entered 'No (N)'	System	15 Aug 2020 12:46:33

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:25', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4177f231-413d-47a5-86fd-99be57473a7b'	System	15 Aug 2020 12:46:33
User entered 'No (N)'	System	15 Aug 2020 12:46:33

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:30', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4177f231-413d-47a5-86fd-99be57473a7b'	System	15 Aug 2020 12:46:33
User entered 'None (1)'	System	15 Aug 2020 12:46:33

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:33', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4177f231-413d-47a5-86fd-99be57473a7b'	System	15 Aug 2020 12:46:33
User entered '15 Aug 2020 08:46'	System	15 Aug 2020 12:46:33

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Aug 2020 15:47'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 2'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:46:25', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c85baafa-a3ef-431f-a275-a94afd7d2866'	System	16 Aug 2020 02:46:48
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 02:46:48

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:46:28', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c85baafa-a3ef-431f-a275-a94afd7d2866'	System	16 Aug 2020 02:46:48
User entered 'No (N)'	System	16 Aug 2020 02:46:48

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:46:34', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c85baafa-a3ef-431f-a275-a94afd7d2866'	System	16 Aug 2020 02:46:48
User entered 'No (N)'	System	16 Aug 2020 02:46:48

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:46:40', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c85baafa-a3ef-431f-a275-a94afd7d2866'	System	16 Aug 2020 02:46:48
User entered 'None (1)'	System	16 Aug 2020 02:46:48

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:46:42', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c85baafa-a3ef-431f-a275-a94afd7d2866'	System	16 Aug 2020 02:46:48
User entered '15 Aug 2020 22:46'	System	16 Aug 2020 02:46:48

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 3'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:30', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'ca29b586-3f46-41ae-a04d-adabfc974ad2'	System	17 Aug 2020 00:43:44
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 00:43:44

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:32', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'ca29b586-3f46-41ae-a04d-adabfc974ad2'	System	17 Aug 2020 00:43:44
User entered 'No (N)'	System	17 Aug 2020 00:43:44

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:34', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'ca29b586-3f46-41ae-a04d-adabfc974ad2'	System	17 Aug 2020 00:43:44
User entered 'No (N)'	System	17 Aug 2020 00:43:44

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:36', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'ca29b586-3f46-41ae-a04d-adabfc974ad2'	System	17 Aug 2020 00:43:44
User entered 'None (1)'	System	17 Aug 2020 00:43:44

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:39', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'ca29b586-3f46-41ae-a04d-adabfc974ad2'	System	17 Aug 2020 00:43:44
User entered '16 Aug 2020 20:43'	System	17 Aug 2020 00:43:44

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 4'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:25:49', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9d63dd0e-c446-47e4-bb34-35d5fdc642e4'	System	17 Aug 2020 20:26:01
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 20:26:01

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:25:51', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9d63dd0e-c446-47e4-bb34-35d5fdc642e4'	System	17 Aug 2020 20:26:01
User entered 'No (N)'	System	17 Aug 2020 20:26:01

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:25:53', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9d63dd0e-c446-47e4-bb34-35d5fdc642e4'	System	17 Aug 2020 20:26:01
User entered 'No (N)'	System	17 Aug 2020 20:26:01

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:25:56', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9d63dd0e-c446-47e4-bb34-35d5fdc642e4'	System	17 Aug 2020 20:26:01
User entered 'None (1)'	System	17 Aug 2020 20:26:01

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:25:59', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9d63dd0e-c446-47e4-bb34-35d5fdc642e4'	System	17 Aug 2020 20:26:01
User entered '17 Aug 2020 16:25'	System	17 Aug 2020 20:26:01

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 5'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:47:56', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '37826c78-5140-4e13-ad8a-9d5657b45da5'	System	18 Aug 2020 18:48:22
User entered 'None (1)'	System	18 Aug 2020 18:48:22

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '37826c78-5140-4e13-ad8a-9d5657b45da5'	System	18 Aug 2020 18:48:22
User entered 'No (N)'	System	18 Aug 2020 18:48:22

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:02', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '37826c78-5140-4e13-ad8a-9d5657b45da5'	System	18 Aug 2020 18:48:22
User entered 'No (N)'	System	18 Aug 2020 18:48:22

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:05', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '37826c78-5140-4e13-ad8a-9d5657b45da5'	System	18 Aug 2020 18:48:22
User entered 'None (1)'	System	18 Aug 2020 18:48:22

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:17', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '37826c78-5140-4e13-ad8a-9d5657b45da5'	System	18 Aug 2020 18:48:22
User entered '18 Aug 2020 14:48'	System	18 Aug 2020 18:48:22

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 6'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:21', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd80bb465-7aeb-4d39-a426-dd08a2421fbe'	System	19 Aug 2020 16:22:36
User entered 'None (1)'	System	19 Aug 2020 16:22:36

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:24', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd80bb465-7aeb-4d39-a426-dd08a2421fbe'	System	19 Aug 2020 16:22:36
User entered 'No (N)'	System	19 Aug 2020 16:22:36

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:27', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd80bb465-7aeb-4d39-a426-dd08a2421fbe'	System	19 Aug 2020 16:22:36
User entered 'No (N)'	System	19 Aug 2020 16:22:36

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:30', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd80bb465-7aeb-4d39-a426-dd08a2421fbe'	System	19 Aug 2020 16:22:36
User entered 'None (1)'	System	19 Aug 2020 16:22:36

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:32', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd80bb465-7aeb-4d39-a426-dd08a2421fbe'	System	19 Aug 2020 16:22:36
User entered '19 Aug 2020 12:22'	System	19 Aug 2020 16:22:36

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 7'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:33:57', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '3c31938b-7195-48e1-ad22-311ad443ac71'	System	20 Aug 2020 16:34:14
User entered 'None (1)'	System	20 Aug 2020 16:34:14

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:33:59', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '3c31938b-7195-48e1-ad22-311ad443ac71'	System	20 Aug 2020 16:34:14
User entered 'No (N)'	System	20 Aug 2020 16:34:14

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:05', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '3c31938b-7195-48e1-ad22-311ad443ac71'	System	20 Aug 2020 16:34:14
User entered 'No (N)'	System	20 Aug 2020 16:34:14

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:08', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '3c31938b-7195-48e1-ad22-311ad443ac71'	System	20 Aug 2020 16:34:14
User entered 'None (1)'	System	20 Aug 2020 16:34:14

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:11', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '3c31938b-7195-48e1-ad22-311ad443ac71'	System	20 Aug 2020 16:34:14
User entered '20 Aug 2020 12:34'	System	20 Aug 2020 16:34:14

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:21', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b252af50-124d-4036-9fdc-f29cd1a96496'	System	14 Aug 2020 16:24:01
User entered 'None (0)'	System	14 Aug 2020 16:24:01

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:25', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b252af50-124d-4036-9fdc-f29cd1a96496'	System	14 Aug 2020 16:24:01
User entered 'None (0)'	System	14 Aug 2020 16:24:01

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:29', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b252af50-124d-4036-9fdc-f29cd1a96496'	System	14 Aug 2020 16:24:01
User entered 'None (0)'	System	14 Aug 2020 16:24:01

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:40', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b252af50-124d-4036-9fdc-f29cd1a96496'	System	14 Aug 2020 16:24:01
User entered 'None (0)'	System	14 Aug 2020 16:24:01

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:43', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b252af50-124d-4036-9fdc-f29cd1a96496'	System	14 Aug 2020 16:24:01
User entered 'None (0)'	System	14 Aug 2020 16:24:01

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:46', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b252af50-124d-4036-9fdc-f29cd1a96496'	System	14 Aug 2020 16:24:01
User entered 'None (0)'	System	14 Aug 2020 16:24:01

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:55', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b252af50-124d-4036-9fdc-f29cd1a96496'	System	14 Aug 2020 16:24:01
User entered 'No (N)'	System	14 Aug 2020 16:24:01

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-14T12:23:58', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b252af50-124d-4036-9fdc-f29cd1a96496'	System	14 Aug 2020 16:24:01
User entered '14 Aug 2020 12:23'	System	14 Aug 2020 16:24:01

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Aug 2020 12:22'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Aug 2020 14:52'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:43', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50d7deae-b459-4e88-ace0-feddd3d95408c'	System	15 Aug 2020 12:47:19
User entered 'None (0)'	System	15 Aug 2020 12:47:19

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:47', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50d7deae-b459-4e88-ace0-feddd3d95408c'	System	15 Aug 2020 12:47:19
User entered 'None (0)'	System	15 Aug 2020 12:47:19

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:56', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50d7deae-b459-4e88-ace0-feddd3d95408c'	System	15 Aug 2020 12:47:19
User entered 'None (0)'	System	15 Aug 2020 12:47:19

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:46:59', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50d7deae-b459-4e88-ace0-feddd3d95408c'	System	15 Aug 2020 12:47:19
User entered 'None (0)'	System	15 Aug 2020 12:47:19

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:47:04', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50d7deae-b459-4e88-ace0-feddd3d95408c'	System	15 Aug 2020 12:47:19
User entered 'None (0)'	System	15 Aug 2020 12:47:19

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:47:08', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50d7deae-b459-4e88-ace0-feddd3d95408c'	System	15 Aug 2020 12:47:19
User entered 'None (0)'	System	15 Aug 2020 12:47:19

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:47:15', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50d7deae-b459-4e88-ace0-feddd3d95408c'	System	15 Aug 2020 12:47:19
User entered 'No (N)'	System	15 Aug 2020 12:47:19

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T08:47:17', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50d7deae-b459-4e88-ace0-feddd3d95408c'	System	15 Aug 2020 12:47:19
User entered '15 Aug 2020 08:47'	System	15 Aug 2020 12:47:19

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Aug 2020 15:47'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 2'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:46:59', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '27b195ef-c373-4607-8f32-197def1a6d02'	System	16 Aug 2020 02:47:51
User entered 'None (0)'	System	16 Aug 2020 02:47:51

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:47:03', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '27b195ef-c373-4607-8f32-197def1a6d02'	System	16 Aug 2020 02:47:51
User entered 'None (0)'	System	16 Aug 2020 02:47:51

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:47:08', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '27b195ef-c373-4607-8f32-197def1a6d02'	System	16 Aug 2020 02:47:51
User entered 'None (0)'	System	16 Aug 2020 02:47:51

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:47:11', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '27b195ef-c373-4607-8f32-197def1a6d02'	System	16 Aug 2020 02:47:51
User entered 'None (0)'	System	16 Aug 2020 02:47:51

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:47:34', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '27b195ef-c373-4607-8f32-197def1a6d02'	System	16 Aug 2020 02:47:51
User entered 'None (0)'	System	16 Aug 2020 02:47:51

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:47:36', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '27b195ef-c373-4607-8f32-197def1a6d02'	System	16 Aug 2020 02:47:51
User entered 'None (0)'	System	16 Aug 2020 02:47:51

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:47:46', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '27b195ef-c373-4607-8f32-197def1a6d02'	System	16 Aug 2020 02:47:51
User entered 'No (N)'	System	16 Aug 2020 02:47:51

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-15T22:47:48', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '27b195ef-c373-4607-8f32-197def1a6d02'	System	16 Aug 2020 02:47:51
User entered '15 Aug 2020 22:47'	System	16 Aug 2020 02:47:51

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 3'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:51', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '835e7c7f-c063-4c55-95a0-f8d87388f566'	System	17 Aug 2020 00:44:12
User entered 'None (0)'	System	17 Aug 2020 00:44:12

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:53', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '835e7c7f-c063-4c55-95a0-f8d87388f566'	System	17 Aug 2020 00:44:12
User entered 'None (0)'	System	17 Aug 2020 00:44:12

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:55', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '835e7c7f-c063-4c55-95a0-f8d87388f566'	System	17 Aug 2020 00:44:12
User entered 'None (0)'	System	17 Aug 2020 00:44:12

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:57', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '835e7c7f-c063-4c55-95a0-f8d87388f566'	System	17 Aug 2020 00:44:12
User entered 'None (0)'	System	17 Aug 2020 00:44:12

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:43:59', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '835e7c7f-c063-4c55-95a0-f8d87388f566'	System	17 Aug 2020 00:44:12
User entered 'None (0)'	System	17 Aug 2020 00:44:12

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:44:01', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '835e7c7f-c063-4c55-95a0-f8d87388f566'	System	17 Aug 2020 00:44:12
User entered 'None (0)'	System	17 Aug 2020 00:44:12

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:44:06', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '835e7c7f-c063-4c55-95a0-f8d87388f566'	System	17 Aug 2020 00:44:12
User entered 'No (N)'	System	17 Aug 2020 00:44:12

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-16T20:44:08', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '835e7c7f-c063-4c55-95a0-f8d87388f566'	System	17 Aug 2020 00:44:12
User entered '16 Aug 2020 20:44'	System	17 Aug 2020 00:44:12

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 4'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:26:05', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a53f8953-93d3-416b-8175-d9ab00b70041'	System	17 Aug 2020 20:26:26
User entered 'None (0)'	System	17 Aug 2020 20:26:26

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:26:10', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a53f8953-93d3-416b-8175-d9ab00b70041'	System	17 Aug 2020 20:26:26
User entered 'None (0)'	System	17 Aug 2020 20:26:26

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:26:12', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a53f8953-93d3-416b-8175-d9ab00b70041'	System	17 Aug 2020 20:26:26
User entered 'None (0)'	System	17 Aug 2020 20:26:26

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:26:14', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a53f8953-93d3-416b-8175-d9ab00b70041'	System	17 Aug 2020 20:26:26
User entered 'None (0)'	System	17 Aug 2020 20:26:26

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:26:16', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a53f8953-93d3-416b-8175-d9ab00b70041'	System	17 Aug 2020 20:26:26
User entered 'None (0)'	System	17 Aug 2020 20:26:26

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:26:18', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a53f8953-93d3-416b-8175-d9ab00b70041'	System	17 Aug 2020 20:26:26
User entered 'None (0)'	System	17 Aug 2020 20:26:26

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:26:21', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a53f8953-93d3-416b-8175-d9ab00b70041'	System	17 Aug 2020 20:26:26
User entered 'No (N)'	System	17 Aug 2020 20:26:26

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-17T16:26:23', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a53f8953-93d3-416b-8175-d9ab00b70041'	System	17 Aug 2020 20:26:26
User entered '17 Aug 2020 16:26'	System	17 Aug 2020 20:26:26

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 5'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:22', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c20220a4-08b9-4fcd-bc53-73f34cd962bb'	System	18 Aug 2020 18:48:46
User entered 'None (0)'	System	18 Aug 2020 18:48:46

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:24', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c20220a4-08b9-4fcd-bc53-73f34cd962bb'	System	18 Aug 2020 18:48:46
User entered 'None (0)'	System	18 Aug 2020 18:48:46

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:26', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c20220a4-08b9-4fcd-bc53-73f34cd962bb'	System	18 Aug 2020 18:48:46
User entered 'None (0)'	System	18 Aug 2020 18:48:46

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:30', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c20220a4-08b9-4fcd-bc53-73f34cd962bb'	System	18 Aug 2020 18:48:46
User entered 'None (0)'	System	18 Aug 2020 18:48:46

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:33', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c20220a4-08b9-4fcd-bc53-73f34cd962bb'	System	18 Aug 2020 18:48:46
User entered 'None (0)'	System	18 Aug 2020 18:48:46

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:37', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c20220a4-08b9-4fcd-bc53-73f34cd962bb'	System	18 Aug 2020 18:48:46
User entered 'None (0)'	System	18 Aug 2020 18:48:46

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:41', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c20220a4-08b9-4fcd-bc53-73f34cd962bb'	System	18 Aug 2020 18:48:46
User entered 'No (N)'	System	18 Aug 2020 18:48:46

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-18T14:48:43', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c20220a4-08b9-4fcd-bc53-73f34cd962bb'	System	18 Aug 2020 18:48:46
User entered '18 Aug 2020 14:48'	System	18 Aug 2020 18:48:46

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 6'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:36', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6a18454d-9980-4905-9c15-83b3bfa2eccd'	System	19 Aug 2020 16:22:57
User entered 'None (0)'	System	19 Aug 2020 16:22:57

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:38', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6a18454d-9980-4905-9c15-83b3bfa2eccd'	System	19 Aug 2020 16:22:57
User entered 'None (0)'	System	19 Aug 2020 16:22:57

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:41', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6a18454d-9980-4905-9c15-83b3bfa2eccd'	System	19 Aug 2020 16:22:57
User entered 'None (0)'	System	19 Aug 2020 16:22:57

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:43', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6a18454d-9980-4905-9c15-83b3bfa2eccd' User entered 'None (0)'	System	19 Aug 2020 16:22:57
	System	19 Aug 2020 16:22:57

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:45', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6a18454d-9980-4905-9c15-83b3bfa2eccd'	System	19 Aug 2020 16:22:57
User entered 'None (0)'	System	19 Aug 2020 16:22:57

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:46', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6a18454d-9980-4905-9c15-83b3bfa2eccd'	System	19 Aug 2020 16:22:57
User entered 'None (0)'	System	19 Aug 2020 16:22:57

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:52', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6a18454d-9980-4905-9c15-83b3bfa2eccd'	System	19 Aug 2020 16:22:57
User entered 'No (N)'	System	19 Aug 2020 16:22:57

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-19T12:22:53', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6a18454d-9980-4905-9c15-83b3bfa2eccd'	System	19 Aug 2020 16:22:57
User entered '19 Aug 2020 12:22'	System	19 Aug 2020 16:22:57

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 7'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:14', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b666a973-31e5-4e09-96ef-2334614fffbf'	System	20 Aug 2020 16:34:34
User entered 'None (0)'	System	20 Aug 2020 16:34:34

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:16', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b666a973-31e5-4e09-96ef-2334614fffbf'	System	20 Aug 2020 16:34:34
User entered 'None (0)'	System	20 Aug 2020 16:34:34

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:18', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b666a973-31e5-4e09-96ef-2334614fffbf'	System	20 Aug 2020 16:34:34
User entered 'None (0)'	System	20 Aug 2020 16:34:34

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:21', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b666a973-31e5-4e09-96ef-2334614fffbf'	System	20 Aug 2020 16:34:34
User entered 'None (0)'	System	20 Aug 2020 16:34:34

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:24', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b666a973-31e5-4e09-96ef-2334614fffbf'	System	20 Aug 2020 16:34:34
User entered 'None (0)'	System	20 Aug 2020 16:34:34

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:25', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b666a973-31e5-4e09-96ef-2334614fffbf'	System	20 Aug 2020 16:34:34
User entered 'None (0)'	System	20 Aug 2020 16:34:34

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:28', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b666a973-31e5-4e09-96ef-2334614fffbf'	System	20 Aug 2020 16:34:34
User entered 'No (N)'	System	20 Aug 2020 16:34:34

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:30', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b666a973-31e5-4e09-96ef-2334614fffbf'	System	20 Aug 2020 16:34:34
User entered '20 Aug 2020 12:34'	System	20 Aug 2020 16:34:34

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:06:03

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	21 Aug 2020 20:33:16

US3302212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '21 Aug 2020'	(b) (4) Wendy Taylor (b) (4)	21 Aug 2020 20:33:16

US3302212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	21 Aug 2020 20:33:16

US3302212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4)	21 Aug 2020 20:33:16
	Wendy Taylor (b) (4)	

US3302212

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	21 Aug 2020 20:33:21

US3302212

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'I'	System	21 Aug 2020 20:33:21

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	28 Aug 2020 20:29:08

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '28 Aug 2020'	(b) (4) Wendy Taylor (b) (4)	28 Aug 2020 20:29:08

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	28 Aug 2020 20:29:08

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4) Wendy Taylor (b) (4)	28 Aug 2020 20:29:08

US3302212

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	28 Aug 2020 20:29:13

US3302212

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'I'	System	28 Aug 2020 20:29:13

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	04 Sep 2020 15:56:09

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '4 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	04 Sep 2020 15:56:09

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	04 Sep 2020 15:56:09

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4)	04 Sep 2020 15:56:09
	Wendy Taylor (b) (4)	

US3302212

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	04 Sep 2020 15:56:02

US3302212

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'I'	System	04 Sep 2020 15:56:02

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:58:19

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:58:19

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:58:19

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'VISIT2'	System	11 Sep 2020 12:58:19

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered 'No (N)'	(b) (4)	
	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '08:36' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '11 Sep 2020 08:36'	System	17 Sep 2020 15:57:48
User entered empty.	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '98.0' F reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '88' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'bpm'	System	17 Sep 2020 15:57:48
User entered empty.	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '18' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'breaths/min'	System	17 Sep 2020 15:57:48
User entered empty.	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '121' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	17 Sep 2020 15:57:48
User entered empty.	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '81' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	(b) (4)	
	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	17 Sep 2020 15:57:48
User entered empty.	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per CDM: Please update time reflect to 24-hour clock format (HH:MM). Thank you' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 15:01:19
Query 'Per CDM: Please update time reflect to 24-hour clock format (HH:MM). Thank you' answered with 'updated ' (Site from DM).	Wendy Taylor (b) (4)	15 Oct 2020 15:00:52
User entered '09:26' reason for change: Data Entry Error	Wendy Taylor (b) (4)	15 Oct 2020 15:00:44
User opened query 'Per CDM: Please update time reflect to 24-hour clock format (HH:MM). Thank you' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:29:29
User entered '9:26'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '11 Sep 2020 09:26'	System	15 Oct 2020 15:00:44
User entered '11 Sep 2020 9:26'	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '98.2' F	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Oral (Oral)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '87'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'bpm'	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '18'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'breaths/min'	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '140'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '93'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:59:04

US3302212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11 Sep 2020'	(b) (4)	11 Sep 2020 12:59:04

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '8:56'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '11 Sep 2020 8:56'	System	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'ONCE'	System	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:58:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:59:32

US3302212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '11 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:59:32

US3302212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '08:45' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:37:28
User entered '8:45'	Brittany Belcher (b) (4)	11 Sep 2020 12:59:32

US3302212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '11 Sep 2020 08:45'	System	06 Nov 2020 15:37:28
User entered '11 Sep 2020 8:45'	System	11 Sep 2020 12:59:32

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:58:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	11 Sep 2020 12:59:46
User entered '11 Sep 2020' reason for change: Data Entry Error	System	11 Sep 2020 12:59:46
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	11 Sep 2020 12:59:41
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '08:43' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:37:34
User entered '8:43'	Brittany Belcher (b) (4)	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '11 Sep 2020 08:43'	System	06 Nov 2020 15:37:34
User entered '11 Sep 2020 8:43'	System	11 Sep 2020 12:59:46
User entered empty.	System	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '08:43' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:37:34
User entered '8:43'	Brittany Belcher (b) (4)	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '11 Sep 2020 08:43'	System	06 Nov 2020 15:37:34
User entered '11 Sep 2020 8:43'	System	11 Sep 2020 12:59:46
User entered empty.	System	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	11 Sep 2020 14:01:25

US3302212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '1'	System	11 Sep 2020 14:01:25

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:11', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9283cc41-9506-4d67-804e-f0e261a09eb4'	System	11 Sep 2020 13:16:38
User entered 'Yes (Y)'	System	11 Sep 2020 13:16:38

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:15', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9283cc41-9506-4d67-804e-f0e261a09eb4' User entered '98.0'	System	11 Sep 2020 13:16:38
	System	11 Sep 2020 13:16:38

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:20', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9283cc41-9506-4d67-804e-f0e261a09eb4'	System	11 Sep 2020 13:16:38
User entered 'No (N)'	System	11 Sep 2020 13:16:38

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:23', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9283cc41-9506-4d67-804e-f0e261a09eb4'	System	11 Sep 2020 13:16:38
User entered '11 Sep 2020 09:16'	System	11 Sep 2020 13:16:38

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '11 Sep 2020 09:16'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '11 Sep 2020 11:46'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '11 Sep 2020 12:41'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 2'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:07:49', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'aa6f035f-3fe7-4c42-af7f-ca0661b5994c'	System	12 Sep 2020 18:08:04
User entered 'Yes (Y)'	System	12 Sep 2020 18:08:04

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:07:53', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'aa6f035f-3fe7-4c42-af7f-ca0661b5994c'	System	12 Sep 2020 18:08:04
User entered '98.2'	System	12 Sep 2020 18:08:04

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:07:57', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'aa6f035f-3fe7-4c42-af7f-ca0661b5994c'	System	12 Sep 2020 18:08:04
User entered 'No (N)'	System	12 Sep 2020 18:08:04

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:08:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'aa6f035f-3fe7-4c42-af7f-ca0661b5994c'	System	12 Sep 2020 18:08:04
User entered '12 Sep 2020 14:08'	System	12 Sep 2020 18:08:04

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 3'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:47:52', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b102c837-f732-43e9-bddc-aa5999d7c2a1'	System	13 Sep 2020 17:48:19
User entered 'Yes (Y)'	System	13 Sep 2020 17:48:19

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:02', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b102c837-f732-43e9-bddc-aa5999d7c2a1'	System	13 Sep 2020 17:48:19
User entered '98.4'	System	13 Sep 2020 17:48:19

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:05', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b102c837-f732-43e9-bddc-aa5999d7c2a1'	System	13 Sep 2020 17:48:19
User entered 'No (N)'	System	13 Sep 2020 17:48:19

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:08', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b102c837-f732-43e9-bddc-aa5999d7c2a1'	System	13 Sep 2020 17:48:19
User entered '13 Sep 2020 13:48'	System	13 Sep 2020 17:48:19

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 4'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T15:57:16', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a11e7f7a-107f-42f7-be1c-e7946d396fbd'	System	14 Sep 2020 19:57:33
User entered 'Yes (Y)'	System	14 Sep 2020 19:57:33

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T15:57:24', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a11e7f7a-107f-42f7-be1c-e7946d396fbd' User entered '98.7'	System	14 Sep 2020 19:57:33
	System	14 Sep 2020 19:57:33

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T15:57:27', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a11e7f7a-107f-42f7-be1c-e7946d396fbd'	System	14 Sep 2020 19:57:33
User entered 'No (N)'	System	14 Sep 2020 19:57:33

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T15:57:29', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a11e7f7a-107f-42f7-be1c-e7946d396fbd'	System	14 Sep 2020 19:57:33
User entered '14 Sep 2020 15:57'	System	14 Sep 2020 19:57:33

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 5'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:20', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '7f873d10-9a52-40a0-94e3-128967d0b6ba'	System	15 Sep 2020 16:32:37
User entered 'Yes (Y)'	System	15 Sep 2020 16:32:37

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:25', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '7f873d10-9a52-40a0-94e3-128967d0b6ba' User entered '98.2'	System	15 Sep 2020 16:32:37
	System	15 Sep 2020 16:32:37

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:27', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '7f873d10-9a52-40a0-94e3-128967d0b6ba'	System	15 Sep 2020 16:32:37
User entered 'No (N)'	System	15 Sep 2020 16:32:37

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:29', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '7f873d10-9a52-40a0-94e3-128967d0b6ba'	System	15 Sep 2020 16:32:37
User entered '15 Sep 2020 12:32'	System	15 Sep 2020 16:32:37

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 6'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 7'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:28', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b6eac27f-b814-48d9-b24a-ccb52587f1ad'	System	11 Sep 2020 13:16:53
User entered 'None (1)'	System	11 Sep 2020 13:16:53

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:31', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b6eac27f-b814-48d9-b24a-ccb52587f1ad'	System	11 Sep 2020 13:16:53
User entered 'No (N)'	System	11 Sep 2020 13:16:53

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:33', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b6eac27f-b814-48d9-b24a-ccb52587f1ad'	System	11 Sep 2020 13:16:53
User entered 'No (N)'	System	11 Sep 2020 13:16:53

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:36', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b6eac27f-b814-48d9-b24a-ccb52587f1ad'	System	11 Sep 2020 13:16:53
User entered 'None (1)'	System	11 Sep 2020 13:16:53

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:39', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b6eac27f-b814-48d9-b24a-ccb52587f1ad'	System	11 Sep 2020 13:16:53
User entered '11 Sep 2020 09:16'	System	11 Sep 2020 13:16:53

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '11 Sep 2020 09:16'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '11 Sep 2020 11:46'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '11 Sep 2020 12:41'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 2'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:08:14', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '943ecf43-231a-446c-a09c-29a5b1458e17'	System	12 Sep 2020 18:08:55
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 18:08:55

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:08:30', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '943ecf43-231a-446c-a09c-29a5b1458e17'	System	12 Sep 2020 18:08:55
User entered 'No (N)'	System	12 Sep 2020 18:08:55

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:08:37', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '943ecf43-231a-446c-a09c-29a5b1458e17'	System	12 Sep 2020 18:08:55
User entered 'No (N)'	System	12 Sep 2020 18:08:55

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:08:40', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '943ecf43-231a-446c-a09c-29a5b1458e17'	System	12 Sep 2020 18:08:55
User entered 'None (1)'	System	12 Sep 2020 18:08:55

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:08:51', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '943ecf43-231a-446c-a09c-29a5b1458e17'	System	12 Sep 2020 18:08:55
User entered '12 Sep 2020 14:08'	System	12 Sep 2020 18:08:55

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 3'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:13', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1766c84d-e671-44e2-8a63-1c7ae7357e2e'	System	13 Sep 2020 17:48:36
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 17:48:36

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:16', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1766c84d-e671-44e2-8a63-1c7ae7357e2e'	System	13 Sep 2020 17:48:36
User entered 'No (N)'	System	13 Sep 2020 17:48:36

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:18', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1766c84d-e671-44e2-8a63-1c7ae7357e2e'	System	13 Sep 2020 17:48:36
User entered 'No (N)'	System	13 Sep 2020 17:48:36

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:22', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1766c84d-e671-44e2-8a63-1c7ae7357e2e'	System	13 Sep 2020 17:48:36
User entered 'None (1)'	System	13 Sep 2020 17:48:36

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:26', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1766c84d-e671-44e2-8a63-1c7ae7357e2e'	System	13 Sep 2020 17:48:36
User entered '13 Sep 2020 13:48'	System	13 Sep 2020 17:48:36

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 4'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T15:57:34', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4fe5f7c5-d095-408c-8349-86f0f6ee95c9'	System	14 Sep 2020 19:57:50
User entered 'None (1)'	System	14 Sep 2020 19:57:50

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T15:57:36', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4fe5f7c5-d095-408c-8349-86f0f6ee95c9'	System	14 Sep 2020 19:57:50
User entered 'No (N)'	System	14 Sep 2020 19:57:50

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T15:57:38', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4fe5f7c5-d095-408c-8349-86f0f6ee95c9'	System	14 Sep 2020 19:57:50
User entered 'No (N)'	System	14 Sep 2020 19:57:50

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T15:57:40', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4fe5f7c5-d095-408c-8349-86f0f6ee95c9'	System	14 Sep 2020 19:57:50
User entered 'None (1)'	System	14 Sep 2020 19:57:50

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T15:57:47', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4fe5f7c5-d095-408c-8349-86f0f6ee95c9'	System	14 Sep 2020 19:57:50
User entered '14 Sep 2020 15:57'	System	14 Sep 2020 19:57:50

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 5'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:33', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0f83399b-5de2-495b-9ab4-f1311d04ecac'	System	15 Sep 2020 16:32:45
User entered 'None (1)'	System	15 Sep 2020 16:32:45

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:35', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0f83399b-5de2-495b-9ab4-f1311d04ecac'	System	15 Sep 2020 16:32:45
User entered 'No (N)'	System	15 Sep 2020 16:32:45

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:37', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0f83399b-5de2-495b-9ab4-f1311d04ecac'	System	15 Sep 2020 16:32:45
User entered 'No (N)'	System	15 Sep 2020 16:32:45

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:39', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0f83399b-5de2-495b-9ab4-f1311d04ecac'	System	15 Sep 2020 16:32:45
User entered 'None (1)'	System	15 Sep 2020 16:32:45

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:42', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0f83399b-5de2-495b-9ab4-f1311d04ecac'	System	15 Sep 2020 16:32:45
User entered '15 Sep 2020 12:32'	System	15 Sep 2020 16:32:45

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 6'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 7'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:44', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b118658a-2fed-4ff2-9051-3de0788a0407'	System	11 Sep 2020 13:17:06
User entered 'None (0)'	System	11 Sep 2020 13:17:06

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:46', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b118658a-2fed-4ff2-9051-3de0788a0407'	System	11 Sep 2020 13:17:06
User entered 'None (0)'	System	11 Sep 2020 13:17:06

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:48', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b118658a-2fed-4ff2-9051-3de0788a0407'	System	11 Sep 2020 13:17:06
User entered 'None (0)'	System	11 Sep 2020 13:17:06

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:50', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b118658a-2fed-4ff2-9051-3de0788a0407'	System	11 Sep 2020 13:17:06
User entered 'None (0)'	System	11 Sep 2020 13:17:06

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:53', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b118658a-2fed-4ff2-9051-3de0788a0407'	System	11 Sep 2020 13:17:06
User entered 'None (0)'	System	11 Sep 2020 13:17:06

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:54', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b118658a-2fed-4ff2-9051-3de0788a0407'	System	11 Sep 2020 13:17:06
User entered 'None (0)'	System	11 Sep 2020 13:17:06

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:16:58', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b118658a-2fed-4ff2-9051-3de0788a0407'	System	11 Sep 2020 13:17:06
User entered 'No (N)'	System	11 Sep 2020 13:17:06

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-11T09:17:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b118658a-2fed-4ff2-9051-3de0788a0407'	System	11 Sep 2020 13:17:06
User entered '11 Sep 2020 09:17'	System	11 Sep 2020 13:17:06

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '11 Sep 2020 09:16'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '11 Sep 2020 11:46'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '11 Sep 2020 12:41'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 2'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:09:02', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'db6f05c9-bca9-4a34-9fc8-ec0d7e612f04'	System	12 Sep 2020 18:09:53
User entered 'None (0)'	System	12 Sep 2020 18:09:53

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:09:09', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'db6f05c9-bca9-4a34-9fc8-ec0d7e612f04'	System	12 Sep 2020 18:09:53
User entered 'No interference with activity (1)'	System	12 Sep 2020 18:09:53

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:09:17', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'db6f05c9-bca9-4a34-9fc8-ec0d7e612f04'	System	12 Sep 2020 18:09:53
User entered 'No interference with activity (1)'	System	12 Sep 2020 18:09:53

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:09:21', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'db6f05c9-bca9-4a34-9fc8-ec0d7e612f04'	System	12 Sep 2020 18:09:53
User entered 'None (0)'	System	12 Sep 2020 18:09:53

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:09:26', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'db6f05c9-bca9-4a34-9fc8-ec0d7e612f04'	System	12 Sep 2020 18:09:53
User entered 'None (0)'	System	12 Sep 2020 18:09:53

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:09:29', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'db6f05c9-bca9-4a34-9fc8-ec0d7e612f04'	System	12 Sep 2020 18:09:53
User entered 'None (0)'	System	12 Sep 2020 18:09:53

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:09:34', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'db6f05c9-bca9-4a34-9fc8-ec0d7e612f04'	System	12 Sep 2020 18:09:53
User entered 'No (N)'	System	12 Sep 2020 18:09:53

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-12T14:09:47', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'db6f05c9-bca9-4a34-9fc8-ec0d7e612f04'	System	12 Sep 2020 18:09:53
User entered '12 Sep 2020 14:09'	System	12 Sep 2020 18:09:53

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 3'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:30', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88ac41b1-4dc6-4afe-b8f6-62751cf8d915'	System	13 Sep 2020 17:48:56
User entered 'None (0)'	System	13 Sep 2020 17:48:56

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:35', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88ac41b1-4dc6-4afe-b8f6-62751cf8d915'	System	13 Sep 2020 17:48:56
User entered 'No interference with activity (1)'	System	13 Sep 2020 17:48:56

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:38', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88ac41b1-4dc6-4afe-b8f6-62751cf8d915'	System	13 Sep 2020 17:48:56
User entered 'None (0)'	System	13 Sep 2020 17:48:56

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:39', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88ac41b1-4dc6-4afe-b8f6-62751cf8d915'	System	13 Sep 2020 17:48:56
User entered 'None (0)'	System	13 Sep 2020 17:48:56

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:41', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88ac41b1-4dc6-4afe-b8f6-62751cf8d915'	System	13 Sep 2020 17:48:56
User entered 'None (0)'	System	13 Sep 2020 17:48:56

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:43', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88ac41b1-4dc6-4afe-b8f6-62751cf8d915'	System	13 Sep 2020 17:48:56
User entered 'None (0)'	System	13 Sep 2020 17:48:56

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:49', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88ac41b1-4dc6-4afe-b8f6-62751cf8d915'	System	13 Sep 2020 17:48:56
User entered 'No (N)'	System	13 Sep 2020 17:48:56

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-13T13:48:52', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88ac41b1-4dc6-4afe-b8f6-62751cf8d915'	System	13 Sep 2020 17:48:56
User entered '13 Sep 2020 13:48'	System	13 Sep 2020 17:48:56

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 4'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T16:01:49', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6181a154-ac20-459f-beff-744f2c7261fb'	System	14 Sep 2020 20:02:10
User entered 'None (0)'	System	14 Sep 2020 20:02:10

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T16:01:51', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6181a154-ac20-459f-beff-744f2c7261fb'	System	14 Sep 2020 20:02:10
User entered 'None (0)'	System	14 Sep 2020 20:02:10

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T16:01:53', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6181a154-ac20-459f-beff-744f2c7261fb' User entered 'None (0)'	System	14 Sep 2020 20:02:10
	System	14 Sep 2020 20:02:10

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T16:01:54', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6181a154-ac20-459f-beff-744f2c7261fb' User entered 'None (0)'	System	14 Sep 2020 20:02:10
	System	14 Sep 2020 20:02:10

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T16:01:55', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6181a154-ac20-459f-beff-744f2c7261fb' User entered 'None (0)'	System	14 Sep 2020 20:02:10
	System	14 Sep 2020 20:02:10

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T16:01:56', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6181a154-ac20-459f-beff-744f2c7261fb'	System	14 Sep 2020 20:02:10
User entered 'None (0)'	System	14 Sep 2020 20:02:10

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T16:02:02', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6181a154-ac20-459f-beff-744f2c7261fb'	System	14 Sep 2020 20:02:10
User entered 'No (N)'	System	14 Sep 2020 20:02:10

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-14T16:02:04', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6181a154-ac20-459f-beff-744f2c7261fb'	System	14 Sep 2020 20:02:10
User entered '14 Sep 2020 16:02'	System	14 Sep 2020 20:02:10

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 5'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:45', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88561255-86af-41da-a503-12b0e3eeb02c'	System	15 Sep 2020 16:33:05
User entered 'None (0)'	System	15 Sep 2020 16:33:05

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:47', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88561255-86af-41da-a503-12b0e3eeb02c'	System	15 Sep 2020 16:33:05
User entered 'None (0)'	System	15 Sep 2020 16:33:05

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:49', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88561255-86af-41da-a503-12b0e3eeb02c'	System	15 Sep 2020 16:33:05
User entered 'None (0)'	System	15 Sep 2020 16:33:05

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:51', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88561255-86af-41da-a503-12b0e3eeb02c'	System	15 Sep 2020 16:33:05
User entered 'None (0)'	System	15 Sep 2020 16:33:05

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:53', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88561255-86af-41da-a503-12b0e3eeb02c'	System	15 Sep 2020 16:33:05
User entered 'None (0)'	System	15 Sep 2020 16:33:05

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:54', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88561255-86af-41da-a503-12b0e3eeb02c'	System	15 Sep 2020 16:33:05
User entered 'None (0)'	System	15 Sep 2020 16:33:05

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:57', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88561255-86af-41da-a503-12b0e3eeb02c'	System	15 Sep 2020 16:33:05
User entered 'No (N)'	System	15 Sep 2020 16:33:05

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90af1bcdadc56982)', Time: '2020-09-15T12:32:59', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '88561255-86af-41da-a503-12b0e3eeb02c'	System	15 Sep 2020 16:33:05
User entered '15 Sep 2020 12:32'	System	15 Sep 2020 16:33:05

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 6'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	11 Sep 2020 12:58:52
User entered 'Day 7'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 12:58:52

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:58:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 12:58:52

US3302212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	21 Sep 2020 15:20:03

US3302212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '21 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	21 Sep 2020 15:20:03

US3302212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	21 Sep 2020 15:20:03

US3302212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4) Wendy Taylor (b) (4)	21 Sep 2020 15:20:03

US3302212

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	21 Sep 2020 15:20:06

US3302212

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'I'	System	21 Sep 2020 15:20:06

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	25 Sep 2020 18:04:48

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '25 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	25 Sep 2020 18:04:48

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	25 Sep 2020 18:04:48

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4) Wendy Taylor (b) (4)	25 Sep 2020 18:04:48

US3302212

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	25 Sep 2020 18:04:50

US3302212

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'I'	System	25 Sep 2020 18:04:50

US3302212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 13:35:28

US3302212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 13:35:28

US3302212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 13:35:28

US3302212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 13:35:28

US3302212

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 13:35:17

US3302212

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'I'	System	02 Oct 2020 13:35:17

US3302212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 13:59:44

US3302212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:37:38
User entered '6 Oct 2020'	Brittany Belcher (b) (4)	06 Oct 2020 13:59:44

US3302212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 13:59:44

US3302212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'VISIT3'	System	06 Oct 2020 13:59:44

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:37:42
User entered '6 Oct 2020'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered '08:51'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '06 Oct 2020 08:51'	System	06 Nov 2020 15:37:42
User entered '6 Oct 2020 08:51'	System	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered '98.0' F	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered 'Oral (Oral)'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered empty.	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered '94'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'bpm'	System	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered '18'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'breaths/min'	System	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered '155'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered '93'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'mmHg'	System	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17

US3302212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:24

US3302212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:39
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:37:48
User entered '6 Oct 2020'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:24

US3302212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:35

US3302212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:37:51
User entered '6 Oct 2020'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:35

US3302212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '08:53'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:35

US3302212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered '06 Oct 2020 08:53'	System	06 Nov 2020 15:37:51
User entered '6 Oct 2020 08:53'	System	06 Oct 2020 14:00:35

US3302212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	06 Oct 2020 14:00:39

US3302212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'I'	System	06 Oct 2020 14:00:39

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 64'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-14T08:42:13', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd0924257-0df6-4cf1-b2ec-3aa504440282'	System	14 Oct 2020 12:42:50
User entered 'Yes (Y)'	System	14 Oct 2020 12:42:50

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-14T08:42:20', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd0924257-0df6-4cf1-b2ec-3aa504440282'	System	14 Oct 2020 12:42:50
User entered 'No (N)'	System	14 Oct 2020 12:42:50

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-14T08:42:31', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd0924257-0df6-4cf1-b2ec-3aa504440282'	System	14 Oct 2020 12:42:50
User entered 'No (N)'	System	14 Oct 2020 12:42:50

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-14T08:42:39', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd0924257-0df6-4cf1-b2ec-3aa504440282'	System	14 Oct 2020 12:42:50
User entered 'No (N)'	System	14 Oct 2020 12:42:50

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-14T08:42:45', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'd0924257-0df6-4cf1-b2ec-3aa504440282'	System	14 Oct 2020 12:42:50
User entered '14 Oct 2020 08:42:45'	System	14 Oct 2020 12:42:50

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 71'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-21T00:01:27', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50f7189f-626f-41c8-a039-fa78b893d485'	System	21 Oct 2020 04:01:45
User entered 'No (N)'	System	21 Oct 2020 04:01:45

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-21T00:01:34', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50f7189f-626f-41c8-a039-fa78b893d485'	System	21 Oct 2020 04:01:45
User entered 'No (N)'	System	21 Oct 2020 04:01:45

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-21T00:01:38', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '50f7189f-626f-41c8-a039-fa78b893d485'	System	21 Oct 2020 04:01:45
User entered '21 Oct 2020 00:01:38'	System	21 Oct 2020 04:01:45

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 78'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-30T09:36:40', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '51ffe0b3-42a4-45be-9a13-09aa2c38bb80'	System	30 Oct 2020 13:36:52
User entered 'No (N)'	System	30 Oct 2020 13:36:52

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-30T09:36:43', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '51ffe0b3-42a4-45be-9a13-09aa2c38bb80'	System	30 Oct 2020 13:36:52
User entered 'No (N)'	System	30 Oct 2020 13:36:52

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-10-30T09:36:46', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '51ffe0b3-42a4-45be-9a13-09aa2c38bb80'	System	30 Oct 2020 13:36:52
User entered '30 Oct 2020 09:36:46'	System	30 Oct 2020 13:36:52

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 92'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-11-13T08:03:54', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f9354105-8f69-41c5-ab15-198adf33e491'	System	13 Nov 2020 13:04:11
User entered 'No (N)'	System	13 Nov 2020 13:04:11

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-11-13T08:04:02', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f9354105-8f69-41c5-ab15-198adf33e491'	System	13 Nov 2020 13:04:11
User entered 'No (N)'	System	13 Nov 2020 13:04:11

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-11-13T08:04:05', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'f9354105-8f69-41c5-ab15-198adf33e491'	System	13 Nov 2020 13:04:11
User entered '13 Nov 2020 08:04:05'	System	13 Nov 2020 13:04:11

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:52:15
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24
Data entry locked.	System	14 Aug 2020 16:06:03
User entered 'Day 99'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 16:06:03

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:18:24
Data entry locked.	System	14 Aug 2020 16:06:03
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 16:06:03

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2020-11-24T15:38:57', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0a9cf91b-77d3-4fac-92df-eaada9443344'	System	24 Nov 2020 20:39:09
User entered 'No (N)'	System	24 Nov 2020 20:39:09

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2020-11-24T15:39:01', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0a9cf91b-77d3-4fac-92df-eaada9443344'	System	24 Nov 2020 20:39:09
User entered 'No (N)'	System	24 Nov 2020 20:39:09

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-11-24T15:39:03', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0a9cf91b-77d3-4fac-92df-eaada9443344'	System	24 Nov 2020 20:39:09
User entered '24 Nov 2020 15:39:03'	System	24 Nov 2020 20:39:09

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2020-11-30T09:56:07', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '95931ca7-4e73-4e75-9174-471e1da0b586'	System	30 Nov 2020 14:56:18
User entered 'No (N)'	System	30 Nov 2020 14:56:18

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2020-11-30T09:56:11', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '95931ca7-4e73-4e75-9174-471e1da0b586'	System	30 Nov 2020 14:56:18
User entered 'No (N)'	System	30 Nov 2020 14:56:18

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-11-30T09:56:13', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '95931ca7-4e73-4e75-9174-471e1da0b586'	System	30 Nov 2020 14:56:18
User entered '30 Nov 2020 09:56:13'	System	30 Nov 2020 14:56:18

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2020-12-06T14:38:39', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '16535aa7-e720-4414-aed4-f1df44b0efbe'	System	06 Dec 2020 19:38:46
User entered 'No (N)'	System	06 Dec 2020 19:38:46

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2020-12-06T14:38:41', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '16535aa7-e720-4414-aed4-f1df44b0efbe'	System	06 Dec 2020 19:38:46
User entered 'No (N)'	System	06 Dec 2020 19:38:46

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-12-06T14:38:43', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '16535aa7-e720-4414-aed4-f1df44b0efbe'	System	06 Dec 2020 19:38:46
User entered '06 Dec 2020 14:38:43'	System	06 Dec 2020 19:38:46

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2020-12-15T10:10:43', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '18570531-0042-47d3-831a-60309426fa8b'	System	15 Dec 2020 15:10:51
User entered 'No (N)'	System	15 Dec 2020 15:10:51

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2020-12-15T10:10:45', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '18570531-0042-47d3-831a-60309426fa8b'	System	15 Dec 2020 15:10:51
User entered 'No (N)'	System	15 Dec 2020 15:10:51

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-12-15T10:10:47', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '18570531-0042-47d3-831a-60309426fa8b'	System	15 Dec 2020 15:10:51
User entered '15 Dec 2020 10:10:47'	System	15 Dec 2020 15:10:51

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2020-12-20T15:06:13', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6f7c1445-9f08-400a-95b4-4c1cb2ab581f'	System	20 Dec 2020 20:06:21
User entered 'No (N)'	System	20 Dec 2020 20:06:21

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2020-12-20T15:06:15', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6f7c1445-9f08-400a-95b4-4c1cb2ab581f'	System	20 Dec 2020 20:06:21
User entered 'No (N)'	System	20 Dec 2020 20:06:21

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-12-20T15:06:18', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '6f7c1445-9f08-400a-95b4-4c1cb2ab581f' User entered '20 Dec 2020 15:06:18'	System	20 Dec 2020 20:06:21
	System	20 Dec 2020 20:06:21

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2020-12-27T11:01:44', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '2e028f14-b35e-4029-89b2-60c4dbd6fa33'	System	27 Dec 2020 16:01:52
User entered 'No (N)'	System	27 Dec 2020 16:01:52

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2020-12-27T11:01:46', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '2e028f14-b35e-4029-89b2-60c4dbd6fa33'	System	27 Dec 2020 16:01:52
User entered 'No (N)'	System	27 Dec 2020 16:01:52

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2020-12-27T11:01:48', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '2e028f14-b35e-4029-89b2-60c4dbd6fa33' User entered '27 Dec 2020 11:01:48'	System	27 Dec 2020 16:01:52
	System	27 Dec 2020 16:01:52

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-01-03T00:02:32', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b63b51e0-19de-49da-868a-98ada23922b0'	System	03 Jan 2021 05:03:06
User entered 'No (N)'	System	03 Jan 2021 05:03:06

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-01-03T00:02:35', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b63b51e0-19de-49da-868a-98ada23922b0'	System	03 Jan 2021 05:03:06
User entered 'No (N)'	System	03 Jan 2021 05:03:06

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-01-03T00:02:38', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b63b51e0-19de-49da-868a-98ada23922b0'	System	03 Jan 2021 05:03:06
User entered '03 Jan 2021 00:02:38'	System	03 Jan 2021 05:03:06

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-01-11T17:37:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '7730cb10-4e91-444f-8609-38880b6b16c1'	System	11 Jan 2021 22:37:08
User entered 'No (N)'	System	11 Jan 2021 22:37:08

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-01-11T17:37:02', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '7730cb10-4e91-444f-8609-38880b6b16c1'	System	11 Jan 2021 22:37:08
User entered 'No (N)'	System	11 Jan 2021 22:37:08

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-01-11T17:37:04', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '7730cb10-4e91-444f-8609-38880b6b16c1'	System	11 Jan 2021 22:37:08
User entered '11 Jan 2021 17:37:04'	System	11 Jan 2021 22:37:08

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-01-19T09:14:05', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '5277cb36-ef37-43f0-9421-dd3c84a4c807'	System	19 Jan 2021 14:14:12
User entered 'No (N)'	System	19 Jan 2021 14:14:12

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-01-19T09:14:07', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '5277cb36-ef37-43f0-9421-dd3c84a4c807'	System	19 Jan 2021 14:14:12
User entered 'No (N)'	System	19 Jan 2021 14:14:12

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-01-19T09:14:09', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '5277cb36-ef37-43f0-9421-dd3c84a4c807'	System	19 Jan 2021 14:14:12
User entered '19 Jan 2021 09:14:09'	System	19 Jan 2021 14:14:12

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-01-24T09:03:11', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'ff329c31-659b-46f8-899d-55befac77d1d'	System	24 Jan 2021 14:03:20
User entered 'No (N)'	System	24 Jan 2021 14:03:20

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-01-24T09:03:14', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'ff329c31-659b-46f8-899d-55befac77d1d'	System	24 Jan 2021 14:03:20
User entered 'No (N)'	System	24 Jan 2021 14:03:20

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-01-24T09:03:17', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'ff329c31-659b-46f8-899d-55befac77d1d'	System	24 Jan 2021 14:03:20
User entered '24 Jan 2021 09:03:17'	System	24 Jan 2021 14:03:20

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-01-31T00:12:01', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '8f8d57dc-3fbd-4ad1-b1c4-12a62cd4f333'	System	31 Jan 2021 05:12:23
User entered 'No (N)'	System	31 Jan 2021 05:12:23

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-01-31T00:12:03', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '8f8d57dc-3fbd-4ad1-b1c4-12a62cd4f333'	System	31 Jan 2021 05:12:23
User entered 'No (N)'	System	31 Jan 2021 05:12:23

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-01-31T00:12:17', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '8f8d57dc-3fbd-4ad1-b1c4-12a62cd4f333'	System	31 Jan 2021 05:12:23
User entered '31 Jan 2021 00:12:17'	System	31 Jan 2021 05:12:23

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-02-07T07:55:49', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '207d3206-bd89-4a7b-b78f-f2e03c3e705e'	System	07 Feb 2021 12:56:00
User entered 'No (N)'	System	07 Feb 2021 12:56:00

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-02-07T07:55:52', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '207d3206-bd89-4a7b-b78f-f2e03c3e705e'	System	07 Feb 2021 12:56:00
User entered 'No (N)'	System	07 Feb 2021 12:56:00

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-02-07T07:55:57', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '207d3206-bd89-4a7b-b78f-f2e03c3e705e'	System	07 Feb 2021 12:56:00
User entered '07 Feb 2021 07:55:57'	System	07 Feb 2021 12:56:00

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-02-15T12:01:46', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a5310405-d3a1-432f-9ec2-4990ad9a1b07'	System	15 Feb 2021 17:08:15
User entered 'No (N)'	System	15 Feb 2021 17:08:15

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-02-15T12:01:48', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a5310405-d3a1-432f-9ec2-4990ad9a1b07'	System	15 Feb 2021 17:08:15
User entered 'No (N)'	System	15 Feb 2021 17:08:15

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-02-15T12:01:50', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a5310405-d3a1-432f-9ec2-4990ad9a1b07'	System	15 Feb 2021 17:08:15
User entered '15 Feb 2021 12:01:50'	System	15 Feb 2021 17:08:15

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-02-21T00:01:29', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1095d6a0-7a1f-4dfa-98ff-4fefddb1e01e'	System	21 Feb 2021 05:02:40
User entered 'No (N)'	System	21 Feb 2021 05:02:40

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-02-21T00:01:34', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1095d6a0-7a1f-4dfa-98ff-4fefddb1e01e'	System	21 Feb 2021 05:02:40
User entered 'No (N)'	System	21 Feb 2021 05:02:40

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-02-21T00:01:39', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1095d6a0-7a1f-4dfa-98ff-4fefddb1e01e'	System	21 Feb 2021 05:02:40
User entered '21 Feb 2021 00:01:39'	System	21 Feb 2021 05:02:40

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-02-28T00:01:46-05:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c4fed6f8-e8f8-4670-aca7-a2555010c20d' User entered 'No (N)'	System	28 Feb 2021 05:03:18
	System	28 Feb 2021 05:03:18

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-02-28T00:01:48-05:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c4fed6f8-e8f8-4670-aca7-a2555010c20d' User entered 'No (N)'	System	28 Feb 2021 05:03:18

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-02-28T00:01:51-05:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c4fed6f8-e8f8-4670-aca7-a2555010c20d' User entered '28 Feb 2021 00:01:51'	System	28 Feb 2021 05:03:18
	System	28 Feb 2021 05:03:18

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-03-08T09:59:34-05:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'df3ee020-57cd-41bb-9ca1-3269613e82f6'	System	08 Mar 2021 14:59:43
User entered 'No (N)'	System	08 Mar 2021 14:59:43

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-03-08T09:59:37-05:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'df3ee020-57cd-41bb-9ca1-3269613e82f6'	System	08 Mar 2021 14:59:43
User entered 'No (N)'	System	08 Mar 2021 14:59:43

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-03-08T09:59:38-05:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'df3ee020-57cd-41bb-9ca1-3269613e82f6'	System	08 Mar 2021 14:59:43
User entered '08 Mar 2021 09:59:38'	System	08 Mar 2021 14:59:43

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-03-14T14:36:11-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4de1f111-1808-49e5-82e3-b4d7cd47a56e'	System	14 Mar 2021 18:36:21
User entered 'No (N)'	System	14 Mar 2021 18:36:21

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-03-14T14:36:13-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4de1f111-1808-49e5-82e3-b4d7cd47a56e'	System	14 Mar 2021 18:36:21
User entered 'No (N)'	System	14 Mar 2021 18:36:21

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-03-14T14:36:15-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '4de1f111-1808-49e5-82e3-b4d7cd47a56e' User entered '14 Mar 2021 14:36:15'	System	14 Mar 2021 18:36:21
	System	14 Mar 2021 18:36:21

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-03-21T01:26:55-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1f5a6984-c0e2-40cd-9d48-251060d16b74'	System	21 Mar 2021 05:27:02
User entered 'No (N)'	System	21 Mar 2021 05:27:02

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-03-21T01:26:57-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1f5a6984-c0e2-40cd-9d48-251060d16b74'	System	21 Mar 2021 05:27:02
User entered 'No (N)'	System	21 Mar 2021 05:27:02

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-03-21T01:26:59-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '1f5a6984-c0e2-40cd-9d48-251060d16b74'	System	21 Mar 2021 05:27:02
User entered '21 Mar 2021 01:26:59'	System	21 Mar 2021 05:27:02

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-03-28T09:48:28-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '458101cb-b6ae-4b38-8454-dd68e18717bf' User entered 'No (N)'	System	28 Mar 2021 13:48:37
	System	28 Mar 2021 13:48:37

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-03-28T09:48:30-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '458101cb-b6ae-4b38-8454-dd68e18717bf' User entered 'No (N)'	System	28 Mar 2021 13:48:37

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-03-28T09:48:32-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '458101cb-b6ae-4b38-8454-dd68e18717bf' User entered '28 Mar 2021 09:48:32'	System	28 Mar 2021 13:48:37
	System	28 Mar 2021 13:48:37

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-04-05T09:47:24-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0bd18bb5-f43a-407f-802d-bcc05897f1e3'	System	05 Apr 2021 13:47:47
User entered 'No (N)'	System	05 Apr 2021 13:47:47

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-04-05T09:47:27-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0bd18bb5-f43a-407f-802d-bcc05897f1e3'	System	05 Apr 2021 13:47:47
User entered 'No (N)'	System	05 Apr 2021 13:47:47

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-04-05T09:47:30-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '0bd18bb5-f43a-407f-802d-bcc05897f1e3'	System	05 Apr 2021 13:47:47
User entered '05 Apr 2021 09:47:30'	System	05 Apr 2021 13:47:47

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-04-15T10:42:06-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a927f2dc-e76f-4d1d-8f9d-968ddf22a428'	System	15 Apr 2021 14:42:15
User entered 'No (N)'	System	15 Apr 2021 14:42:15

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-04-15T10:42:08-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a927f2dc-e76f-4d1d-8f9d-968ddf22a428'	System	15 Apr 2021 14:42:15
User entered 'No (N)'	System	15 Apr 2021 14:42:15

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-04-15T10:42:10-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a927f2dc-e76f-4d1d-8f9d-968ddf22a428'	System	15 Apr 2021 14:42:15
User entered '15 Apr 2021 10:42:10'	System	15 Apr 2021 14:42:15

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-04-20T19:36:02-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c1b7f046-b973-496e-a0a9-e6f9a236b06d' User entered 'No (N)'	System	20 Apr 2021 23:36:16
	System	20 Apr 2021 23:36:16

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-04-20T19:36:03-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c1b7f046-b973-496e-a0a9-e6f9a236b06d'	System	20 Apr 2021 23:36:16
User entered 'No (N)'	System	20 Apr 2021 23:36:16

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-04-20T19:36:05-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'c1b7f046-b973-496e-a0a9-e6f9a236b06d'	System	20 Apr 2021 23:36:16
User entered '20 Apr 2021 19:36:05'	System	20 Apr 2021 23:36:16

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-04-26T12:16:17-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9dd7f0ca-3e46-4632-a8a8-b8d74b5fa20b'	System	26 Apr 2021 16:16:27
User entered 'No (N)'	System	26 Apr 2021 16:16:27

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-04-26T12:16:19-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9dd7f0ca-3e46-4632-a8a8-b8d74b5fa20b'	System	26 Apr 2021 16:16:27
User entered 'No (N)'	System	26 Apr 2021 16:16:27

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-04-26T12:16:22-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '9dd7f0ca-3e46-4632-a8a8-b8d74b5fa20b'	System	26 Apr 2021 16:16:27
User entered '26 Apr 2021 12:16:22'	System	26 Apr 2021 16:16:27

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[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 (300ae00e3aa28bff)', Time: '2021-05-03T11:31:10-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '778533dd-48fb-4db8-9b0d-7494934159bf'	System	03 May 2021 15:31:21
User entered 'No (N)'	System	03 May 2021 15:31:21

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

Have you been exposed to someone with 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 (300ae00e3aa28bff)', Time: '2021-05-03T11:31:11-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '778533dd-48fb-4db8-9b0d-7494934159bf'	System	03 May 2021 15:31:21
User entered 'No (N)'	System	03 May 2021 15:31:21

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-05-03T11:31:13-04:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: '778533dd-48fb-4db8-9b0d-7494934159bf'	System	03 May 2021 15:31:21
User entered '03 May 2021 11:31:13'	System	03 May 2021 15:31:21

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:58:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:18:24

US3302212

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:58:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-02-28T00:01:58-05:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a844f85b-fbb1-4ad9-b159-52ae5d507f4c'	System	28 Feb 2021 05:03:41
User entered 'No (N)'	System	28 Feb 2021 05:03:41

US3302212

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:58:18

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300ae00e3aa28bff)', Time: '2021-02-28T00:02:01-05:00', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'a844f85b-fbb1-4ad9-b159-52ae5d507f4c'	System	28 Feb 2021 05:03:41
User entered '28 Feb 2021 00:02:01'	System	28 Feb 2021 05:03:41

US3302212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 15:10:18

US3302212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '6 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 15:10:18

US3302212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Nov 2020 15:10:18

US3302212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:10:18

US3302212

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:10:21

US3302212

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:48:17
User entered 'I'	System	06 Nov 2020 15:10:21

US3302212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:52:17

US3302212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '10 Dec 2020'	(b) (4), (b) (6)	06 Jan 2021 15:52:17

US3302212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 15:52:17

US3302212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 15:52:17

US3302212

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:52:22

US3302212

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered 'I'	System	06 Jan 2021 15:52:22

US3302212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:52:32

US3302212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '6 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 15:52:32

US3302212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 15:52:32

US3302212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 15:52:32

US3302212

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:52:36

US3302212

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered 'I'	System	06 Jan 2021 15:52:36

US3302212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	05 Feb 2021 15:02:22

US3302212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '05 Feb 2021'	(b) (4) Wendy Taylor (b) (4)	05 Feb 2021 15:02:22

US3302212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	05 Feb 2021 15:02:22

US3302212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered empty.	(b) (4) Wendy Taylor (b) (4)	05 Feb 2021 15:02:22

US3302212

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	05 Feb 2021 15:02:28

US3302212

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered 'I'	System	05 Feb 2021 15:02:28

US3302212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:17:42

US3302212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:17:42

US3302212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:17:42

US3302212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered 'VISIT4'	System	17 Mar 2021 15:17:42

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:23
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered '16 Mar 2021'	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:26
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered '13:42'	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered '16 Mar 2021 13:42'	System	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:28
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered '98.0' F	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:30
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:31
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:32
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered '88'	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered 'bpm'	System	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:34
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered '18'	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered 'breaths/min'	System	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:35
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered '131'	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered 'mmHg'	System	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:54:38
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:53:57
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 15:55:28
User entered '88'	(b) (4), (b) (6)	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered 'mmHg'	System	31 Mar 2021 17:21:14

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46

US3302212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:58:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46

US3302212

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:17:54

US3302212

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:58:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:17:54

US3302212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:18:03

US3302212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:18:03

US3302212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered '13:45'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:18:03

US3302212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered '16 Mar 2021 13:45'	System	17 Mar 2021 15:18:03

US3302212

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 15:18:06

US3302212

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:41:46
User entered 'I'	System	17 Mar 2021 15:18:06

US3302212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:44:22
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	06 Apr 2021 13:20:16

US3302212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:44:22
User entered '06 Apr 2021'	Kendal Nelson (b) (4)	06 Apr 2021 13:20:16

US3302212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:44:22
User entered 'Contact Made (CONTACT MADE)'	Kendal Nelson (b) (4)	06 Apr 2021 13:20:16

US3302212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:58:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:44:22
User entered empty.	Kendal Nelson (b) (4)	06 Apr 2021 13:20:16

US3302212

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:15
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:44:22
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	06 Apr 2021 13:20:21

US3302212

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:58:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:51:15
User entered 'I'	System	06 Apr 2021 13:20:21

US3302212

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

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 15:25:41

US3302212

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

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 15:25:41

US3302212

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

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:25:41

US3302212

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

Form: Visit Date

Generated On: 09 Jun 2021 16:58:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User entered 'UNBLND_DECIDE'	System	17 Feb 2021 15:25:41

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 15:25:57

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:38:27

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 15:25:57

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	20 Apr 2021 17:54:12
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 09:07:44
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:20:51
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 18:20:37
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:20:37
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:02:01
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered empty. WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:38:27

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 15:25:57

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	17 Feb 2021 15:25:57

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	17 Feb 2021 15:25:57

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	17 Feb 2021 15:25:57

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'No (N)'	(b) (4), (b) (6)	17 Feb 2021 15:25:57

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User entered empty.	System	17 Feb 2021 15:25:57

US3302212

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

Form: Unblinding

Generated On: 09 Jun 2021 16:58:18

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User entered empty.	System	17 Feb 2021 15:25:57

US3302212

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 15:26:10

US3302212

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 15:26:10

US3302212

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '13:49'	(b) (4), (b) (6)	17 Feb 2021 15:26:10

US3302212

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User entered '16 Feb 2021 13:49'	System	17 Feb 2021 15:26:10

US3302212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:58:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 15:26:18

US3302212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 15:26:18

US3302212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:58:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '13:47'	(b) (4), (b) (6)	17 Feb 2021 15:26:18

US3302212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:12:40
User entered '16 Feb 2021 13:47'	System	17 Feb 2021 15:26:18

US3302212

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:58:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:15:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:41
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Oct 2020 13:28:55

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:56:51
User entered	System	07 Oct 2020 11:56:48
'USA-US087-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	07 Oct 2020 11:56:48

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
User closed query 'Per DM CLR: Please note that this is also recorded in the MH eCRF. Please review and ensure that there is no duplicate recording. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 06:55:43
Query 'Per DM CLR: Please note that this is also recorded in the MH eCRF. Please review and ensure that there is no duplicate recording. ' answered with 'updated. ' (Site from DM).	Brittany Belcher (b) (4)	28 Jan 2021 15:05:46
User opened query 'Per DM CLR: Please note that this is also recorded in the MH eCRF. Please review and ensure that there is no duplicate recording. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 23:34:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:09:09
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:05:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 15:05:47
Data point term sent to Coder	System	13 Nov 2020 14:33:48
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 14:33:21
Coding entries removed.	(b) (4), (b) (6)	13 Nov 2020 14:33:21
User entered 'worsening cervical radiculopathy' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 14:33:21
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 14:12:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 14:12:21

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EAB) (1725)

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	06 Oct 2020 13:38:18
User entered 'Herniated Disc'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 14:56:40
User closed query 'Due to a query from the Medical Monitors the response to this question was revised from No to Yes. Please review source and revise in source also, so that the Monitor can SDV the data.' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 14:56:29
Query 'Due to a query from the Medical Monitors the response to this question was revised from No to Yes. Please review source and revise in source also, so that the Monitor can SDV the data.' answered with 'Source updated and now matches EDC. ' (Site from CRA).	Brittany Belcher (b) (4)	31 Mar 2021 21:44:54
User opened query 'Due to a query from the Medical Monitors the response to this question was revised from No to Yes. Please review source and revise in source also, so that the Monitor can SDV the data.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 19:58:41
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
User closed query 'Per sponsor review, narrative reports medical attention for SAE. Please update field accordingly. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 06:55:53
Query 'Per sponsor review, narrative reports medical attention for SAE. Please update field accordingly. ' answered with 'updated. ' (Site from DM).	Brittany Belcher (b) (4)	28 Jan 2021 15:06:18
DataPoint Un-verified.	Brittany Belcher (b) (4)	28 Jan 2021 15:06:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	28 Jan 2021 15:06:11
User opened query 'Per sponsor review, narrative reports medical attention for SAE. Please update field accordingly. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:46:23
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:41:34
User closed query 'Please review and revise if needed. In source this AE was answered as "No" for "I this a MAAE?"' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:41:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Query 'Please review and revise if needed. In source this AE was answered as "No" for "I this a MAAE?"' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	06 Nov 2020 18:02:18
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 18:01:46
User opened query 'Please review and revise if needed. In source this AE was answered as "No" for "I this a MAAE?"' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 19:21:03
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:06
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 10:27:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:41:58
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 18:02:20
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 18:01:46
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 18:01:46
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:31:12
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'No (N)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:38:44
User closed query 'Please review source and revise if needed. Source states start date as 05Aug2020.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:38:36
Query 'Please review source and revise if needed. Source states start date as 05Aug2020.' answered with 'source updated.' (Site from CRA).	brittany cooksey (b) (4)	19 Nov 2020 13:47:20
	(b) (4)	
User opened query 'Please review source and revise if needed. Source states start date as 05Aug2020.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 18:10:20
User closed query 'Adverse Event Start Date is before System treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).		13 Nov 2020 20:17:50
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify.' (Site from System).	System	13 Nov 2020 20:17:50
User entered '28 Sep 2020' reason for change: Data Entry Error	Wendy Taylor (b) (4)	13 Nov 2020 20:17:50
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	13 Nov 2020 14:33:21
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify.' (Site from System).		13 Nov 2020 14:33:21
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 14:33:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '05 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 14:33:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 02:58:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 21:59:54
User entered '28 Sep 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 21:59:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Nov 2020 19:57:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Nov 2020 19:57:25
User entered 'UN Aug 2020' (non-conformant).	Wendy Taylor (b) (4)	06 Nov 2020 19:57:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Nov 2020 19:56:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Nov 2020 19:56:40
DataPoint Un-verified.	Wendy Taylor (b) (4)	06 Nov 2020 19:56:40
User entered '00 Aug 2020' (non-conformant).	Wendy Taylor (b) (4)	06 Nov 2020 19:56:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:42:23
User closed query 'Please review source and revise if needed. In source this AE start date is listed as UN-Aug-2020.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:42:20
Query 'Please review source and revise if needed. In source this AE start date is listed as UN-Aug-2020.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	06 Nov 2020 18:02:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Nov 2020 18:01:46
User entered 'un Aug 2020' (non-conformant).	brittany cooksey (b) (4)	06 Nov 2020 18:01:46
User opened query 'Please review source and revise if needed. In source this AE start date is listed as UN-Aug-2020.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 19:28:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Please review source and revise if needed. In source this AE start date is listed as 28Sep2020.' canceled (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 19:27:43
User opened query 'Please review source and revise if needed. In source this AE start date is listed as 28Sep2020.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 19:22:25
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 19:21:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '28 Sep 2020'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'No (N)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 02:58:35
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 21:59:54
	(b) (4)	
User entered '30 Sep 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 21:59:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 19:42:45
User closed query 'Please review source and revise if needed. In source this AE end date is listed as 28Sep2020.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:42:39
Query 'Please review source and revise if needed. In source this AE end date is listed as 28Sep2020.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	06 Nov 2020 18:02:13
	(b) (4)	
User entered '28 Sep 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 18:01:46
	(b) (4)	
User opened query 'Please review source and revise if needed. In source this AE end date is listed as 28Sep2020.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 19:27:17
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 19:22:52
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '30 Sep 2020'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '0'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '0'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'I'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '28 Sep 2020'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '30 Sep 2020'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'No (N)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '0'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '0'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '0'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'Not Related (NOT RELATED)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'Not Related (NOT RELATED)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:40:40
User closed query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:36:11
Query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.'	brittany cooksey (b) (4)	06 Nov 2020 18:03:07
answered with 'updated' (Site from Safety).	(b) (4)	
DataPoint Un-verified.	brittany cooksey (b) (4)	06 Nov 2020 18:01:46
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	brittany cooksey (b) (4)	06 Nov 2020 18:01:46
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
	(b) (4), (b) (6)	
User opened query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		16 Oct 2020 13:38:51
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 13:39:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 13:39:27
User entered 'None (NONE)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Oct 2020 13:39:27
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 13:38:08
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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None

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '0'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
User closed query 'Per CDM-Concomitant Medication is ticked, however, no Concomitant Medication is recorded with indication stating ae as 'WORSENING CERVICAL RADICULOPATHY' on conmed page. Kindly consider to verify and update the ae with corresponding indication on conmed page.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 06:09:11
Query 'Per CDM-Concomitant Medication is ticked, however, no Concomitant Medication is recorded with indication stating ae as 'WORSENING CERVICAL RADICULOPATHY' on conmed page. Kindly consider to verify and update the ae with corresponding indication on conmed page.Thank you.' answered with 'updated' (Site from DM).	Wendy Taylor (b) (4)	23 Dec 2020 03:18:52
User opened query 'Per CDM-Concomitant Medication is ticked, however, no Concomitant Medication is recorded with indication stating ae as 'WORSENING CERVICAL RADICULOPATHY' on conmed page. Kindly consider to verify and update the ae with corresponding indication on conmed page.Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:12:38
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'I'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:40:47
DataPoint Un-verified.	Wendy Taylor (b) (4)	06 Nov 2020 19:58:02
User entered '1' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 19:58:02
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '0'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide results XR spinal cervical exam performed in the OR. Please keep query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 14:43:39
Query 'PV Query: Please provide results XR spinal cervical exam performed in the OR. Please keep query open until information is received.' answered with 'Per hospital, no intraoperative X-ray was performed. No report to upload.' (Site from Safety).	Brittany Belcher (b) (4)	22 Mar 2021 18:45:40
User opened query 'PV Query: Please provide results XR spinal cervical exam performed in the OR. Please keep query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 13:15:07
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:41:55
User closed query 'PV Query: Please provide results XR spinal cervical exam performed in the OR.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 16:11:21
Query 'PV Query: Please provide results XR spinal cervical exam performed in the OR.' answered with 'sent release for XR' (Site from Safety).	Wendy Taylor (b) (4)	04 Mar 2021 23:31:57
User opened query 'PV Query: Please provide results XR spinal cervical exam performed in the OR.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 18:43:16
User closed query 'PV Query: Please provide results XR spinal cervical exam performed in the OR.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 15:10:05
Query 'PV Query: Please provide results XR spinal cervical exam performed in the OR.' answered with 'Per medical records, uploaded in the source and faxed to safety team, Page 1 of records include the Impression/results of XR spinal cervical exam. Does this result need to be noted in the narrative?' (Site from Safety).	Brittany Belcher (b) (4)	28 Jan 2021 15:13:04
User opened query 'PV Query: Please provide results XR spinal cervical exam performed in the OR.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 20:35:40

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: No records have been received. Please re-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)	19 Jan 2021 14:01:11
Query 'PV Query: No records have been received. Please provide any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:01:09
Query 'PV Query: No records have been received. Please re-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 'these were resent today ' (Site from Safety).	Wendy Taylor (b) (4)	15 Jan 2021 15:58:53
User opened query 'PV Query: No records have been received. Please provide any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 19:19:34
User opened query 'PV Query: No records have been received. Please re-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)	29 Dec 2020 19:18:37
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)	28 Dec 2020 22:28:34
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 22:28:31

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records were send' (Site from Safety).	Wendy Taylor (b) (4)	23 Dec 2020 03:19:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'records were emailed' (Site from Safety).	Wendy Taylor (b) (4)	23 Dec 2020 03:19:30
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)	25 Nov 2020 14:40:19
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 14:40:14
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:35
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:04:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:04:37
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:04:34
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:04:31

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Folder: Adverse Events

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[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. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:04:28
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'records reviewed and updates made' (Site from Safety).	brittany cooksey (b) (4)	19 Nov 2020 13:52:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'records reviewed and updates have been made' (Site from Safety).	brittany cooksey (b) (4)	19 Nov 2020 13:51:53
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'all records reviewed and updated' (Site from Safety).	brittany cooksey (b) (4)	19 Nov 2020 13:51:30
DataPoint Un-verified.	brittany cooksey (b) (4)	19 Nov 2020 13:50:53
User entered 'PT CAME IN FOR VISIT 3 AND REPORTED THAT HE HAD A CERVICAL FUSION TO REPAIR A HERNIATED DISC ON 28SEP2020 AND WAS ADMITTED AND DISCHARGED ON 30SEP2020 ALL AE'S WERE UPDATED AND SAE WAS REPORTED. CONMEDS WERE UPDATED AND MEDICAL RECORDS WERE REQUESTED. FINAL FOLLOW UP WILL BE COMPLETED ONCE RECORDS ARE RECEIVED. Records were received and updates made to source and EDC' reason for change: Data Entry Error	brittany cooksey (b) (4)	19 Nov 2020 13:50:53
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no COVID testing done' (Site from Safety).	brittany cooksey (b) (4)	19 Nov 2020 13:48:39

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'this has been emailed' (Site from Safety).	brittany cooksey (b) (4) (b) (4)	19 Nov 2020 13:48:22
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) (b) (4)	16 Nov 2020 17:30:06
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	16 Nov 2020 17:26:17
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	16 Nov 2020 17:26:00
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	16 Nov 2020 17:25:41
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	16 Nov 2020 17:25:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	09 Nov 2020 19:36:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:58:18

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:36:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:36:37
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:36:25
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'awaiting records' (Site from Safety).	brittany cooksey (b) (4)	06 Nov 2020 18:01:23
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'awaiting records' (Site from Safety).	brittany cooksey (b) (4)	06 Nov 2020 18:01:18
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'awaiting records' (Site from Safety).	brittany cooksey (b) (4)	06 Nov 2020 18:01:12
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'awaiting records' (Site from Safety).	brittany cooksey (b) (4)	06 Nov 2020 18:01:08
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:39:46

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:39:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:39:28
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:39:18
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Oct 2020 13:43:48
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	06 Oct 2020 13:43:48
User entered 'Pt came in for visit 3 and reported that he had a cervical fusion to repair a herniated disc on 28SEP2020 and was admitted and discharged on 30SEP2020 all AE's were updated and SAE was reported. Conmeds were updated and medical records were requested. Final follow up will be completed once records are received.' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Oct 2020 13:43:48
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Oct 2020 13:38:08
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 15:06:11
User entered '0'	System	06 Nov 2020 18:01:46
User entered '1'	System	06 Oct 2020 13:38:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Oct 2020 13:38:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:15:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:29:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Oct 2020 13:44:38
User entered 'No (N)'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
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)	23 Dec 2020 17:43:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 17:43:39
Data point term sent to Coder	System	23 Dec 2020 03:18:47
Coding entries removed.	Wendy Taylor (b) (4)	23 Dec 2020 03:18:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
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)	06 Oct 2020 14:13:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:13:02
Data point term sent to Coder	System	06 Oct 2020 13:46:35
User entered 'Oxycodone'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered 'No (N)'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:00:40
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Un-verified.	(b) (4) Wendy Taylor (b) (4)	23 Dec 2020 03:18:26
User entered 'worsening cervical radiculopathy' reason for change: Data Entry Error	Wendy Taylor (b) (4)	23 Dec 2020 03:18:26
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered 'herniated disc'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	09 Apr 2021 12:44:22
Signature has been broken.	(b) (4) Brittany Belcher (b) (4)	07 Apr 2021 12:24:52
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered '5'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered 'mg (mg)'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered 'as needed (PRN)'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered 'Oral (ORAL)'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered '28 Sep 2020'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered '0'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered 'No (N)'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered '30 Sep 2020'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 20:00:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 11:19:11
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4) (b) (4)	07 Dec 2020 21:55:51
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	07 Dec 2020 21:55:42
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	07 Dec 2020 21:55:42
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:35:40
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Oct 2020 13:45:48

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User entered empty.	System	06 Oct 2020 13:45:48

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User entered empty.	System	06 Oct 2020 13:45:48

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:59
User entered empty.	System	06 Oct 2020 13:45:48

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
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)	14 Nov 2020 06:21:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Nov 2020 06:21:45
Data point term sent to Coder	System	13 Nov 2020 14:16:24
User entered 'Dexamethasone'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:52:31
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Patient reports receiving entered medication as Surgical Procedure Anesthesia. Entered as correct.' (Site from DM).	Brittany Belcher (b) (4)	25 Jan 2021 19:48:51
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:17:22
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '8'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User entered empty.	System	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User entered empty.	System	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:12
User entered empty.	System	13 Nov 2020 14:16:00

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 06:31:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 06:31:53
Data point term sent to Coder	System	13 Nov 2020 14:17:24
User entered 'Ephedrine'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:52:34
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Patient reports receiving entered medication as Surgical Procedure Anesthesia. Entered as correct.' (Site from DM).	Brittany Belcher (b) (4)	25 Jan 2021 19:49:08
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:17:43
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '5'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User entered empty.	System	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User entered empty.	System	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:17
User entered empty.	System	13 Nov 2020 14:16:34

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:33:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:33:45
Data point term sent to Coder	System	13 Nov 2020 14:17:25
User entered 'Fentanyl'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '100'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'ug (ug)'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User entered empty.	System	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User entered empty.	System	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:22
User entered empty.	System	13 Nov 2020 14:17:04

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: GLYCOPYRRONIUM, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:38:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:38:06
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
Data point term sent to Coder	System	13 Nov 2020 14:18:25
User entered 'Glycopyrrolate'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:52:42
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Patient reports receiving entered medication as Surgical Procedure Anesthesia. Entered as correct.' (Site from DM).	Brittany Belcher (b) (4)	25 Jan 2021 19:55:09
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:18:03
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0.2'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User entered empty.	System	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User entered empty.	System	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:28
User entered empty.	System	13 Nov 2020 14:17:44

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:17:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:17:46
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 14:19:26
User entered 'Hydromorphone'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0.8'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User entered empty.	System	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User entered empty.	System	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:34
User entered empty.	System	13 Nov 2020 14:18:29

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:08:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:08:45
Data point term sent to Coder	System	13 Nov 2020 14:20:30
User entered 'Ketamine'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '50'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User entered empty.	System	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User entered empty.	System	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:38
User entered empty.	System	13 Nov 2020 14:19:31

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:08:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:08:45
Data point term sent to Coder	System	13 Nov 2020 14:20:30
User entered 'Lidocaine'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '80'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User entered empty.	System	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User entered empty.	System	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:42
User entered empty.	System	13 Nov 2020 14:20:06

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:19:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:19:44
Data point term sent to Coder	System	13 Nov 2020 14:21:37
User entered 'Midazolam'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '2'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User entered empty.	System	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User entered empty.	System	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:47
User entered empty.	System	13 Nov 2020 14:20:36

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
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)	14 Nov 2020 06:02:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:02:47
Data point term sent to Coder	System	13 Nov 2020 14:21:36
User entered 'Ondansetron'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 07:18:59
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Per source, con med is correct as listed.' (Site from DM).	Brittany Belcher (b) (4)	26 Jan 2021 16:32:46
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 07:21:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '4'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User entered empty.	System	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User entered empty.	System	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:51
User entered empty.	System	13 Nov 2020 14:21:17

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 06:00:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 06:00:46
Data point term sent to Coder	System	13 Nov 2020 14:22:38
User entered 'Propofol'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '230'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User entered empty.	System	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User entered empty.	System	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:08
User entered empty.	System	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:59:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:59:45
Data point term sent to Coder	System	13 Nov 2020 14:23:39
User entered 'Rocuronium'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 07:22:20
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Patient reports receiving entered medication as Surgical Procedure Anesthesia. Entered as correct.' (Site from DM).	Brittany Belcher (b) (4)	25 Jan 2021 19:50:14
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:20:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:04:59
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Per source, dosage correct as listed.' (Site from DM).	Brittany Belcher (b) (4)	26 Jan 2021 16:34:45
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 07:22:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '5'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User entered empty.	System	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User entered empty.	System	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:41
User entered empty.	System	13 Nov 2020 14:22:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: CHOLINE DERIVATIVES, PRODUCT: SUXAMETHONIUM, PRODUCTSYNONYM: SUCCINYLCHOLINE [SUXAMETHONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:58:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:58:45
Data point term sent to Coder	System	13 Nov 2020 14:27:43
User entered 'Succinylcholine'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '100'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User entered empty.	System	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User entered empty.	System	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:46
User entered empty.	System	13 Nov 2020 14:27:12

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: REMIFENTANIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:15:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:15:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: REMIFENTANIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:00:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:00:46
Data point term sent to Coder	System	13 Nov 2020 14:27:43
User entered 'Remifentanil'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '1.95'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User entered empty.	System	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User entered empty.	System	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:35
User entered empty.	System	13 Nov 2020 14:27:39

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:21:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:21:47
Data point term sent to Coder	System	13 Nov 2020 14:30:44
User entered 'Cefazolin'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:51:33
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Patient reports receiving entered medication as Surgical Procedure Anesthesia. Entered as correct.' (Site from DM).	Brittany Belcher (b) (4)	25 Jan 2021 19:50:32
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:17:06
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '2'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'g (g)'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User entered empty.	System	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User entered empty.	System	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:31:04
User entered empty.	System	13 Nov 2020 14:29:45

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 14:47:46
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 14:47:46
Data point term sent to Coder	System	13 Nov 2020 14:30:44
User entered 'Phenylephrine'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 10:51:26
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Patient reports receiving entered medication as Surgical Procedure Anesthesia. Entered as correct.' (Site from DM).	Brittany Belcher (b) (4)	25 Jan 2021 19:50:43
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:19:17
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '4280'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'ug (ug)'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User entered empty.	System	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User entered empty.	System	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:32:18
User entered empty.	System	13 Nov 2020 14:30:21

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
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)	13 Nov 2020 14:32:45
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	13 Nov 2020 14:32:45
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	13 Nov 2020 14:31:47
User entered 'Acetaminophen'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '1000'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User entered empty.	System	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User entered empty.	System	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:36
User entered empty.	System	13 Nov 2020 14:30:50

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:36:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:36:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
Data point term sent to Coder	System	13 Nov 2020 14:31:45
User entered 'Lactaded Ringers Infusion Premix'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 10:51:16
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Patient reports receiving entered medication as Surgical Procedure Anesthesia. Entered as correct.' (Site from DM).	Brittany Belcher (b) (4)	25 Jan 2021 19:50:57
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:18:43
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical prep'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '1000'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mL (mL)'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:58:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:58:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:15:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:22:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Oct 2020 13:43:59
User entered 'No (N)'	Brittany Belcher (b) (4)	17 Aug 2020 23:14:03

US3302212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:58:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:31:34
User entered '28 Sep 2020'	Wendy Taylor (b) (4)	06 Oct 2020 13:44:30

US3302212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:58:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:31:34
User entered 'Cervical Fusion'	Wendy Taylor (b) (4)	06 Oct 2020 13:44:30

US3302212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 02:44:59
User closed query 'Please review source and revise if needed. Source states indication as "Medical History". You stated that it was updated, but it does not show it. Please update again and press Save.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 02:44:55
Query 'Please review source and revise if needed. Source states indication as "Medical History". You stated that it was updated, but it does not show it. Please update again and press Save.' answered with 'source updated to AE' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 22:16:35
	(b) (4)	
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:25:05
User opened query 'Please review source and revise if needed. Source states indication as "Medical History". You stated that it was updated, but it does not show it. Please update again and press Save.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:37:53
User closed query 'Please review source and revise if needed. Source states indication as "Medical History"' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:37:53
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	06 Nov 2020 19:58:47
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'updated' (Site from DM).	Wendy Taylor (b) (4)	06 Nov 2020 19:58:44
Query 'Please review source and revise if needed. Source states indication as "Medical History"' answered with 'updated' (Site from CRA).	Wendy Taylor (b) (4)	06 Nov 2020 19:58:25

US3302212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:58:18

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:58:42
User opened query 'Please review source and revise if needed. Source states indication as "Medical History"' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 19:32:37
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 19:31:56
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:31:34
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	06 Oct 2020 13:44:30
User entered 'Adverse Event (AE)'	Wendy Taylor (b) (4)	06 Oct 2020 13:44:30

US3302212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:58:18

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 19:23:48
DataPoint Un-verified.	Wendy Taylor (b) (4)	06 Nov 2020 19:58:47
User entered empty; reason for change Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 19:58:47
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:31:34
User entered 'Herniated Dics'	Wendy Taylor (b) (4)	06 Oct 2020 13:44:30

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'USA-US087-2020-MRNA-1273-P301000002'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Gregory'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Feldman'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '141 Harold Fleming Court'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Spartanburg'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '29303'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:38:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered 'US'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Mar 2021 14:44:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
User entered '6'	System	29 Jan 2021 15:10:42
User entered '5'	System	20 Nov 2020 22:05:22
User entered '4'	System	16 Nov 2020 20:54:43
User entered '3'	System	12 Nov 2020 00:55:11
User entered '2'	System	09 Nov 2020 19:39:10
User entered '1'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'USA-US087-2020-MRNA-1273-P301000002'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Gregory'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Feldman'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '141 Harold Fleming Court'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Spartanburg'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '29303'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:38:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered 'US'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Mar 2021 14:44:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
User entered '6'	System	29 Jan 2021 15:10:42
User entered '5'	System	20 Nov 2020 22:05:22
User entered '4'	System	16 Nov 2020 20:54:43
User entered '3'	System	12 Nov 2020 00:55:11
User entered '2'	System	09 Nov 2020 19:39:10
User entered '1'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:58:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered '07/Oct/2020 07:57'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:58:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:38:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'USA-US087-2020-MRNA-1273-P301000002'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Gregory'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Feldman'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '141 Harold Fleming Court'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Spartanburg'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '29303'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:38:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered 'US'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Mar 2021 14:44:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
User entered '6'	System	29 Jan 2021 15:10:42
User entered '5'	System	20 Nov 2020 22:05:22
User entered '4'	System	16 Nov 2020 20:54:43
User entered '3'	System	12 Nov 2020 00:55:11
User entered '2'	System	09 Nov 2020 19:39:10
User entered '1'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:58:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 03:23:40
User entered '09/Nov/2020 19:39'	System	09 Nov 2020 19:39:10

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:58:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 03:23:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:39:31
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 19:39:10

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'USA-US087-2020-MRNA-1273-P301000002'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Gregory'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Feldman'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '141 Harold Fleming Court'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Spartanburg'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '29303'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:38:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered 'US'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Mar 2021 14:44:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
User entered '6'	System	29 Jan 2021 15:10:42
User entered '5'	System	20 Nov 2020 22:05:22
User entered '4'	System	16 Nov 2020 20:54:43
User entered '3'	System	12 Nov 2020 00:55:11
User entered '2'	System	09 Nov 2020 19:39:10
User entered '1'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:58:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:12:40
User entered '12/Nov/2020 00:55'	System	12 Nov 2020 00:55:11

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:58:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 22:05:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:12:40
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 00:55:11

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'USA-US087-2020-MRNA-1273-P301000002'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Gregory'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Feldman'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '141 Harold Fleming Court'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Spartanburg'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '29303'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:38:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered 'US'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Mar 2021 14:44:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
User entered '6'	System	29 Jan 2021 15:10:42
User entered '5'	System	20 Nov 2020 22:05:22
User entered '4'	System	16 Nov 2020 20:54:43
User entered '3'	System	12 Nov 2020 00:55:11
User entered '2'	System	09 Nov 2020 19:39:10
User entered '1'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:58:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:12:40
User entered '16/Nov/2020 20:54'	System	16 Nov 2020 20:54:43

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:58:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 22:05:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:12:40
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 20:54:43

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'USA-US087-2020-MRNA-1273-P301000002'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Gregory'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Feldman'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '141 Harold Fleming Court'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Spartanburg'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '29303'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:38:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered 'US'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Mar 2021 14:44:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
User entered '6'	System	29 Jan 2021 15:10:42
User entered '5'	System	20 Nov 2020 22:05:22
User entered '4'	System	16 Nov 2020 20:54:43
User entered '3'	System	12 Nov 2020 00:55:11
User entered '2'	System	09 Nov 2020 19:39:10
User entered '1'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:58:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:50:18
User entered '20/Nov/2020 22:05'	System	20 Nov 2020 22:05:22

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:58:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 15:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 19:50:18
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 22:05:22

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'USA-US087-2020-MRNA-1273-P301000002'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Gregory'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Feldman'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '141 Harold Fleming Court'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Spartanburg'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '29303'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:38:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered 'US'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Mar 2021 14:44:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
User entered '6'	System	29 Jan 2021 15:10:42
User entered '5'	System	20 Nov 2020 22:05:22
User entered '4'	System	16 Nov 2020 20:54:43
User entered '3'	System	12 Nov 2020 00:55:11
User entered '2'	System	09 Nov 2020 19:39:10
User entered '1'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:58:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:59:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered '29/Jan/2021 10:10'	(b) (4) System	29 Jan 2021 15:10:42

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:58:18

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)	31 Mar 2021 19:59:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 15:10:42

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'USA-US087-2020-MRNA-1273-P301000002'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Yes (Y)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'No (N)'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Gregory'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Feldman'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '141 Harold Fleming Court'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered 'Spartanburg'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 19:18:10
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 11:57:06
User entered '29303'	System	07 Oct 2020 11:56:48

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:38:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:18:10
User entered 'US'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 16:58:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	23 Mar 2021 14:44:04
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 18:55:29
	(b) (4)	
User entered '6'	System	29 Jan 2021 15:10:42
User entered '5'	System	20 Nov 2020 22:05:22
User entered '4'	System	16 Nov 2020 20:54:43
User entered '3'	System	12 Nov 2020 00:55:11
User entered '2'	System	09 Nov 2020 19:39:10
User entered '1'	System	07 Oct 2020 11:57:12

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:58:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:59:31
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered '23/Mar/2021 10:44'	(b) (4) System	23 Mar 2021 14:44:04

US3302212

Folder: SAE USA-US087-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:58:18

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)	31 Mar 2021 19:59:31
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:07:19
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 14:44:04