

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

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:56:01

All time stamps listed in this document are displayed in GMT

US3302212

Form: Participant Creation

Generated On: 26 Nov 2020 10:56:01

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:56:01

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:01

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)

Generated On: 26 Nov 2020 10:56:01

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)

Generated On: 26 Nov 2020 10:56:01

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: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

Condition	WORSENING CERVICAL RADICULOPATHY
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: Vital Signs

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

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)

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:01

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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 ☒

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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 ☒

US3302212

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

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)

Generated On: 26 Nov 2020 10:56:01

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)

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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 <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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

Generated On: 26 Nov 2020 10:56:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	11 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 10:56:01

Collection date (<i>dd MMM yyyy</i>)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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 ☐

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:01

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 ☐

US3302212

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	06 OCT 2020
Collection time (<i>00:00-23:59</i>)	08:53 (24 HR)
Collection date and time (derived)	06 OCT 2020 08:53

US3302212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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 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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	24 DEC 2020 23:59
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US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	26 AUG 2021 23:59
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US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	07 APR 2022 23:59
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US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 10:56:01

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

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	25 AUG 2022 23:59
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US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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 <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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3302212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

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 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3302212

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3302212

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:56:01

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)

Generated On: 26 Nov 2020 10:56:01

AEID	USA-US087-2020-MRNA-1273-P30 1000002
Adverse event	WORSENING CERVICAL RADICULOPATHY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	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"/>
Number of Days in ICU	

v6.020 DTW (1102)

336 of 1916

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

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)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:56:01

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)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	OXYCODONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HERNIATED DISC
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

	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 checked="" type="checkbox"/>
	No	<input 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 (2)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	8
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	EPHEDRINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	FENTANYL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	100
Dose unit	mg <input type="checkbox"/> ug <input checked="" type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	GLYCOPYRROLATE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	0.2
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	HYDROMORPHONE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	0.8
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:01

	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)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	KETAMINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	50
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	LIDOCAINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	80
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	MIDAZOLAM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	2
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	ONDANSETRON
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	4
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	PROPOFOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	230
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	PROPOFOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	1382.33
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	ROCURONIUM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	SUCCINYLCHOLINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	100
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	REMIFENTANIL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	1.95
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	CEFAZOLIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	PHENYLEPHRINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	4280
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PROCEDURE ANESTHESIA
Dose per administration	1000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:01

	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 (19)

Generated On: 26 Nov 2020 10:56:01

Name of Medication	LACTADED RINGERS INFUSION PREMIX
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SURGICAL PREP
Dose per administration	1000
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input checked="" type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:56:01

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

US3302212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:56:01

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3302212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:56:01

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

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

Generated On: 26 Nov 2020 10:56:01

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)	5

US3302212

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:01

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)	5
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)

Generated On: 26 Nov 2020 10:56:01

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)	5
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)

Generated On: 26 Nov 2020 10:56:01

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)	5
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)

Generated On: 26 Nov 2020 10:56:01

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)	5
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)

Generated On: 26 Nov 2020 10:56:01

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)	5
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

Audit

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

US3302212

Form: Participant Creation

Generated On: 26 Nov 2020 10:56:01

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3302212'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Aug 2020 14:59:50

US3302212

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:12

US3302212

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Aug 2020 14:59:51

US3302212

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:12

US3302212

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Aug 2020 15:44:12

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1986'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Aug 2020 14:59:52

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[Age](#)

Audit	User	Time (GMT)
User entered '34'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '34'	System	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

White

Audit	User	Time (GMT)
User entered '1'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[Black](#)

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[Other](#)

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:01

Not reported

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:44:39

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:02

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Aug 2020 14:59:51

US3302212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 15:45:13

US3302212

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:56:01

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:13

US3302212

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:56:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(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: 26 Nov 2020 10:56:01

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Apr 2020'	System	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 13:28:51

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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) (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 13:29:05

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:01

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Apr 2020'	System	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 13:29:25

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:19:16
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) (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) (b) (4)	13 Nov 2020 15:05:47
Data point term sent to Coder	System	13 Nov 2020 13:29:46
User entered 'Worsening Cervical Radiculopathy'	(b) (4), (b) (6)	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:19:17
User entered '05 Aug 2020'	(b) (4), (b) (6)	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:19:19
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:19:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:19:22
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:19:24
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 13:29:46

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '11:01'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:01'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

Height (xxx.x)

Audit	User	Time (GMT)
User entered '72' in	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: 26 Nov 2020 10:56:01

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '205' lb	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: 26 Nov 2020 10:56:01

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Temperature (xxx.x)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 10:56:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	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: 26 Nov 2020 10:56:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brittany Belcher (b) (4)	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4) [REDACTED]	06 Oct 2020 17:05:53
User entered '77'	Brittany Belcher (b) (4) [REDACTED]	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4) [REDACTED]	06 Oct 2020 17:05:53
User entered '16'	Brittany Belcher (b) (4) [REDACTED]	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4) [REDACTED]	06 Oct 2020 17:05:53
User entered '140'	Brittany Belcher (b) (4) [REDACTED]	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	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: 26 Nov 2020 10:56:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:11:36

US3302212

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	17 Aug 2020 23:11:42

US3302212

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

No Risk Identified

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 18:22:42
User entered '1'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48
	(b) (4)	

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 18:22:42
	(b) (4)	
User entered '0'	brittany cooksey (b) (4)	14 Aug 2020 15:45:48
	(b) (4)	

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

[Other](#)

Audit	User	Time (GMT)
User entered '0'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:01

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:45:48

US3302212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:05

US3302212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:05

US3302212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:05

US3302212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	14 Aug 2020 15:46:05

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Aug 2020 15:44:40

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:01

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 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) [REDACTED]	14 Aug 2020 15:44:40

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Aug 2020 15:44:40

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:01

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 15:46:29

US3302212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:01

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 10:56:01

Height

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 10:56:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	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: 26 Nov 2020 10:56:01

Height

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 10:56:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	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 (1)

Generated On: 26 Nov 2020 10:56:01

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	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: 26 Nov 2020 10:56:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '11:01' 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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F 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: 26 Nov 2020 10:56:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' 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: 26 Nov 2020 10:56:01

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77' 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: 26 Nov 2020 10:56:01

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '16' 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: 26 Nov 2020 10:56:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140' 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: 26 Nov 2020 10:56:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '86' 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: 26 Nov 2020 10:56:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Height

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 10:56:01

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	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: 26 Nov 2020 10:56:01

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:30:36
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '18'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '118'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 23:12:45

US3302212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Brittany Belcher (b) (4)	17 Aug 2020 23:12:51

US3302212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Brittany Belcher (b) (4)	17 Aug 2020 23:12:51

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '12:02'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:02'	System	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	brittany cooksey (b) (4) (b) (4)	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 16:06:03

US3302212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:18

US3302212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:18

US3302212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:28'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:18

US3302212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:29

US3302212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:01

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 10:56:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	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: 26 Nov 2020 10:56:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	17 Aug 2020 23:13:50

US3302212

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 23:13:50

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	18 Aug 2020 18:48:14
User entered '98.2'	System	18 Aug 2020 18:48:14

US3302212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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-fedd3d95408c'	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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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-fedd3d95408c'	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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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-fedd3d95408c'	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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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-fed3d95408c'	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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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-2334614ffffbd'	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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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-2334614ffffbd'	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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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-2334614ffffbd'	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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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-2334614ffffbd'	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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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-2334614ffffbd'	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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (56caa3542e23771b)', Time: '2020-08-20T12:34:28', User OID: 'PatientReportedOutcome (US3302212)', ODM File OID: 'b666a973-31e5-4e09-96ef-2334614ffffbd'	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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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-2334614ffffbd'	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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	21 Aug 2020 20:33:16

US3302212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Wendy Taylor (b) (4)	21 Aug 2020 20:33:16

US3302212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	21 Aug 2020 20:33:16

US3302212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Wendy Taylor (b) (4)	21 Aug 2020 20:33:16

US3302212

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	21 Aug 2020 20:33:21

US3302212

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 20:33:21

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	28 Aug 2020 20:29:08

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Wendy Taylor (b) (4)	28 Aug 2020 20:29:08

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	28 Aug 2020 20:29:08

US3302212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Wendy Taylor (b) (4)	28 Aug 2020 20:29:08

US3302212

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	28 Aug 2020 20:29:13

US3302212

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 20:29:13

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	04 Sep 2020 15:56:09

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Wendy Taylor (b) (4)	04 Sep 2020 15:56:09

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	04 Sep 2020 15:56:09

US3302212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Wendy Taylor (b) (4)	04 Sep 2020 15:56:09

US3302212

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	04 Sep 2020 15:56:02

US3302212

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 15:56:02

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	11 Sep 2020 12:58:19

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Brittany Belcher (b) (4)	11 Sep 2020 12:58:19

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	11 Sep 2020 12:58:19

US3302212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	11 Sep 2020 12:58:19

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered 'No (N)'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020' reason for change: Data Entry Error	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '08:36' reason for change: Data Entry Error	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F reason for change: Data Entry Error	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '88' reason for change: Data Entry Error	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '18' reason for change: Data Entry Error	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: 26 Nov 2020 10:56:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121' reason for change: Data Entry Error	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81' reason for change: Data Entry Error	marsha gossett (b) (4)	17 Sep 2020 15:57:48
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '87'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '18'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '93'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 14:01:21

US3302212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	11 Sep 2020 12:59:04

US3302212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Brittany Belcher (b) (4)	11 Sep 2020 12:59:04

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered empty.	Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

What was the treatment time? (00:00-23:59)

Audit	User	Time (GMT)
User entered '8:56'	Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 12:58:52

US3302212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	11 Sep 2020 12:59:32

US3302212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Brittany Belcher (b) (4)	11 Sep 2020 12:59:32

US3302212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:45' reason for change: Data Entry Error	(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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	11 Sep 2020 12:59:46
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	Brittany Belcher (b) (4) [REDACTED]	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) [REDACTED]	11 Sep 2020 12:59:41

US3302212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:01

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '08:43' reason for change: Data Entry Error	(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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 10:56:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '08:43' reason for change: Data Entry Error	(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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	11 Sep 2020 14:01:25

US3302212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 14:01:25

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	11 Sep 2020 13:16:38
User entered '98.0'	System	11 Sep 2020 13:16:38

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	14 Sep 2020 19:57:33
User entered '98.7'	System	14 Sep 2020 19:57:33

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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' User entered '14 Sep 2020 15:57'	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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	15 Sep 2020 16:32:37
User entered '98.2'	System	15 Sep 2020 16:32:37

US3302212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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' User entered '14 Sep 2020 16:02'	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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	21 Sep 2020 15:20:03

US3302212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Wendy Taylor (b) (4)	21 Sep 2020 15:20:03

US3302212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	21 Sep 2020 15:20:03

US3302212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Wendy Taylor (b) (4)	21 Sep 2020 15:20:03

US3302212

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	21 Sep 2020 15:20:06

US3302212

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 15:20:06

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	25 Sep 2020 18:04:48

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Wendy Taylor (b) (4)	25 Sep 2020 18:04:48

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	25 Sep 2020 18:04:48

US3302212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Wendy Taylor (b) (4)	25 Sep 2020 18:04:48

US3302212

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	25 Sep 2020 18:04:50

US3302212

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 18:04:50

US3302212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 13:35:28

US3302212

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 13:35:17

US3302212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	06 Oct 2020 13:59:44

US3302212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '06 Oct 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 10:56:01

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	06 Oct 2020 13:59:44

US3302212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	06 Oct 2020 13:59:44

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '08:51'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '94'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered '18'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '155'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '93'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 14:00:15

US3302212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:01

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:24

US3302212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 10:56:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:35

US3302212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 10:56:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:53'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:35

US3302212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	06 Oct 2020 14:00:39

US3302212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 14:00:39

US3302212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[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: '2020-10-14T08:42:13', 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: 26 Nov 2020 10:56:01

Have you been exposed to someone with 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: '2020-10-14T08:42:20', 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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 10:56:01

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[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: '2020-10-21T00:01:27', 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: 26 Nov 2020 10:56:01

Have you been exposed to someone with 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: '2020-10-21T00:01:34', 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: 26 Nov 2020 10:56:01

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[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: '2020-10-30T09:36:40', 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: 26 Nov 2020 10:56:01

[Have you been exposed to someone with 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: '2020-10-30T09:36:43', 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: 26 Nov 2020 10:56:01

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[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: '2020-11-13T08:03:54', 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: 26 Nov 2020 10:56:01

[Have you been exposed to someone with 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: '2020-11-13T08:04:02', 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: 26 Nov 2020 10:56:01

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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 Oct 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: 26 Nov 2020 10:56:01

[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 Oct 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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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 Oct 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: 26 Nov 2020 10:56:01

[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 Oct 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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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 Oct 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: 26 Nov 2020 10:56:01

[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 Oct 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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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 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: 26 Nov 2020 10:56:01

[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 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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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 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: 26 Nov 2020 10:56:01

[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 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: 26 Nov 2020 10:56:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:18:24
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:18:24

US3302212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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 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: 26 Nov 2020 10:56:01

[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 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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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

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Have you been exposed to someone with 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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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

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[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:10:18

US3302212

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 15:10:21

US3302212

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 15:10:21

US3302212

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:56:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 'USA-US087-2020-mRNA-1273-P301000002'	System	07 Oct 2020 11:56:48
User entered 'New'	(b) (4), (b) (6)	07 Oct 2020 11:56:48

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Adverse event](#)

Audit	User	Time (GMT)
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) (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) (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) (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) (b) (4)	06 Oct 2020 14:12:21
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
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
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	(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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 10:27:00
	(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). DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 18:02:20
	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). DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 07:31:12
	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'No (N)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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 beforeSystem 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 System 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 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 System 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
User entered '05 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 14:33:21

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Please review source and revise if needed. In source this AE start date is listed as 28Sep2020.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 19:22:25
	(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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'No (N)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 02:58:35
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 21:59:54
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:59:54
DataPoint Verified.	brittany cooksey (b) (4)	10 Nov 2020 21:59:54
DataPoint Verified.	(b) (4)	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
User entered '28 Sep 2020' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:01:46
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Death](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Life threatening](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '1'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered 'No (N)'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered empty.	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Other medically important event](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(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.' answered with 'updated' (Site from Safety).	brittany cooksey (b) (4)	06 Nov 2020 18:03:07
DataPoint Un-verified.	brittany cooksey (b) (4)	06 Nov 2020 18:01:46
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 18:01:46
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
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).	(b) (4), (b) (6)	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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[None](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:19:01
User entered '1'	Wendy Taylor (b) (4)	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)

Generated On: 26 Nov 2020 10:56:01

[Narrative](#)

Audit	User	Time (GMT)
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
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Narrative](#)

Audit	User	Time (GMT)
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). DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	19 Nov 2020 13:51:30
	brittany cooksey (b) (4) (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) (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) (b) (4)	19 Nov 2020 13:48:39
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

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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 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 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)	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)	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)	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)	09 Nov 2020 19:36:48
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Narrative](#)

Audit	User	Time (GMT)
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
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Narrative](#)

Audit	User	Time (GMT)
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)

Generated On: 26 Nov 2020 10:56:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 18:01:46
User entered '1'	System	06 Oct 2020 13:38:08

US3302212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4) (b) (4)	06 Oct 2020 13:45:48

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 19:30:46
User entered '5'	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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:01

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

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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) (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) (b) (4), (b) (6) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	14 Nov 2020 06:17:46
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 06:17:46
Data point term sent to Coder	System	13 Nov 2020 14:19:26
User entered 'Hydromorphone'	(b) (4), (b) (6) (b) (4), (b) (6) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4), (b) (6) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:21:41

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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 14:22:37
User entered 'Propofol'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'surgical procedure anesthesia'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '1382.33'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:22:15

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (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 14:27:43
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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
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
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	13 Nov 2020 14:32:45
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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If frequency is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	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) (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 'Lactated 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: 26 Nov 2020 10:56:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:56:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:22:37
User entered '28 Sep 2020'	(b) (4), (b) (6)	13 Nov 2020 14:31:32

US3302212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:56:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	10 Nov 2020 22:16:35
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: 26 Nov 2020 10:56:01

[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: 26 Nov 2020 10:56:01

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:56:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:56:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	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: 26 Nov 2020 10:56:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:56:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

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)	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: 26 Nov 2020 10:56:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:56:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	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: 26 Nov 2020 10:56:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:56:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	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: 26 Nov 2020 10:56:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 10:56:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 10:56:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 10:56:01

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)	23 Nov 2020 19:50:18
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 22:05:22