

US3112262 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3112262

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

[Participant ID](#)

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

US3112262

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:04:29

Generated On: 09 Jun 2021 15:12:19

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 17:04:13

Generated On: 09 Jun 2021 15:12:19

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 17:04:13

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 17:04:14

Generated On: 09 Jun 2021 15:12:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 17:04:14

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 17:04:14

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 17:04:14

Generated On: 09 Jun 2021 15:12:19

Condition	CORONARY ARTERY DISEASE/STATUS POST STENT
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	30 SEP 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	SEP 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:04:29

Generated On: 09 Jun 2021 15:12:19

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>)	11:07 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:07
Height (<i>xxx.x</i>)	170 cm
Weight (<i>xxx.x</i>)	104.5 kg
BMI (<i>xxx.x</i>)	36.15917 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 17:04:14

Generated On: 09 Jun 2021 15:12:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:04:29

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

PRODUCTION MANAGER AT
PRINTING COMPANY

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:04:29

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

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

What was the participant's randomization number? 186378

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

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)	11:07 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:07
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

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)	13:13 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:13
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:12:32

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Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:40 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 12:40

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	11:47 (24 HR)
Collection date and time (derived)	14 AUG 2020 11:47

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	14 AUG 2020 11:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 13:15

PC Open Date & Time

14 AUG 2020 13:05

PC Close Date & Time

14 AUG 2020 15:35

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 94.9 °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 19:03
PC Open Date & Time	14 AUG 2020 16:30
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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 19:12

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 20:18

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

17 AUG 2020 19:48

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: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

18 AUG 2020 18:59

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

19 AUG 2020 19:28

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

20 AUG 2020 19:05

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 13:16

PC Open Date & Time

14 AUG 2020 13:05

PC Close Date & Time

14 AUG 2020 15:35

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 19:06

PC Open Date & Time

14 AUG 2020 16:30

PC Close Date & Time

15 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 19:13

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 20:19

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 19:48

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 19:00

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 19:28

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 19:05

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 13:17
PC Open Date & Time	14 AUG 2020 13:05
PC Close Date & Time	14 AUG 2020 15:35

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 19:06
PC Open Date & Time	14 AUG 2020 16:30
PC Close Date & Time	15 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:14
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:19
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 19:49
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 1996

EAB) (1725)

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 19:02
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 19:29
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 19:05
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3112262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:47:49

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:47:49

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:47:49

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:47:49

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:47:49

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:47:49

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

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)	11:49 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:49
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:01
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3112262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

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.

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 SEP 2020

What was the treatment time? (00:00-23:59) 13:22 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 13:22

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

What was the frequency of the study treatment dosing? ONCE

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

US3112262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	12:35 (24 HR)
Collection date and time (derived)	11 SEP 2020 12:35

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:00	11 SEP 2020 12:00
Nasopharyngeal Swab 2	No		

US3112262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 SEP 2020 13:42

PC Close Date & Time

11 SEP 2020 16:12

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	11 SEP 2020 18:02
PC Open Date & Time	11 SEP 2020 17:07
PC Close Date & Time	12 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	12 SEP 2020 18:40
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.6 °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

13 SEP 2020 19:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

14 SEP 2020 22:06

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

15 SEP 2020 20:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 19:35

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 19:26

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 13:42

PC Close Date & Time

11 SEP 2020 16:12

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:02

PC Open Date & Time

11 SEP 2020 17:07

PC Close Date & Time

12 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 18:42

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 19:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 22:07

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 20:17

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 19:36

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 19:26

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

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

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

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 13:42

PC Close Date & Time

11 SEP 2020 16:12

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 18:03
PC Open Date & Time	11 SEP 2020 17:07
PC Close Date & Time	12 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

89 of 1996

EAB) (1725)

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:55
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

91 of 1996

EAB) (1725)

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:48
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

93 of 1996

EAB) (1725)

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 22:07
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

95 of 1996

EAB) (1725)

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:17
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 1996

EAB) (1725)

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 19:36
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 1996

EAB) (1725)

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:27
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3112262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:47:49

Generated On: 09 Jun 2021 15:12:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112262

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:47:49

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112262

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:32 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 11:32
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3112262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	9 OCT 2020 11:55

US3112262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:12:32

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 11:11:27

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 00:38:25

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

28 OCT 2020 12:03:14

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

11 NOV 2020 09:32:39

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 00:09:42
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 00:02:27

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 00:01:48

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 10:31:35

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 00:01:45

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 18:58:27

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 17:24:17

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 00:02:42

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 12:26:37
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 00:22:55

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 00:09:12

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 21:14:32

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 00:02:16
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 02:04:41
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 22:03:12
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 17:43:09

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 11:23:32

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 10:56:03

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 00:18:01

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 23:02:44

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 11:40:36

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 00:54:57

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 00:39:30

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:51:30

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 09:11:34

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

Patient Cloud Open Date & Time	25 JUL 2021 00:01
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Patient Cloud Close Date & Time	29 JUL 2021 23:59
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US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

Patient Cloud Open Date & Time	26 SEP 2021 00:01
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Patient Cloud Close Date & Time	30 SEP 2021 23:59
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US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

Patient Cloud Open Date & Time	14 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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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US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 642

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <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

US3112262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:12:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 17:43:23

US3112262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:53:34

Generated On: 09 Jun 2021 15:12:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 06 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112262

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:53:34

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112262

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112262

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112262

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	12 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:40 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 10:40
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>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3112262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	12 MAR 2021
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Collection time (00:00-23:59)	10:55 (24 HR)
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Collection date and time (derived)	12 MAR 2021 10:55
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US3112262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112262

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112262

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:12:19

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"/>

US3112262

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:12:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	6 JAN 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Date of updated informed consent (<i>dd MMM yyyy</i>)	6 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	6 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Height	170 cm
Weight	233.4 lb
BMI (xxx.x)	36.70966

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Height	170 cm
Weight	233.4 lb
BMI (xxx.x)	36.70966
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)	6 JAN 2021
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 10:06
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Height	170 cm
Weight	233.4 lb
BMI (xxx.x)	36.70966
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)	6 JAN 2021
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 11:29
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 6 JAN 2021

What was the treatment time? (00:00-23:59) 10:58 (24 HR)

Treatment Date and Time (derived) 6 JAN 2021 10:58

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	6 JAN 2021
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Collection time (00:00-23:59)	10:23 (24 HR)
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Collection date and time (derived)	6 JAN 2021 10:23
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US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	10:19
Collection Date and Time (derived)	6 JAN 2021 10:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112262

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3112262

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

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)	3 FEB 2021
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 15:06
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	3 FEB 2021
Time of assessment (00:00-23:59)	15:52 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 15:52
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3112262

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3112262

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 3 FEB 2021

What was the treatment time? (00:00-23:59) 15:21 (24 HR)

Treatment Date and Time (derived) 3 FEB 2021 15:21

Which arm was used to give treatment? Left Arm ☒
Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3112262

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112262

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112262

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	12 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:40 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 10:40
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>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112262

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:21:05

Generated On: 09 Jun 2021 15:12:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3112262

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 MAR 2021
Collection time (<i>00:00-23:59</i>)	10:55 (24 HR)
Collection date and time (derived)	12 MAR 2021 10:55

US3112262

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 00:10:01

Generated On: 09 Jun 2021 15:12:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

AEID	USA-US062-2021-MRNA-1273-P30 1000016
Adverse event	SEPTICEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	31 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

ABDOMINAL DISCOMFORT
STARTING 26MAR2021 LED TO
BLOOD WORK WITH
ABNORMAL LIVER FUNCTION
VALUES. ADMITTED ON
28MAR2021, POSITIVE E.COLI
CULTURE AND ADMITTED FOR
SEPTICEMIA AND PRESCRIBED
ANTIBIOTICS. DISCHARGED ON
31MAR2021 WITH CONTINUING
ANTIBIOTICS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 5000

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☒
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 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) 12 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA VIRUS
PROPHYLAXIS

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 1996

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

Name of Medication SHINGRIX

Prophylaxis Yes ☒
No ☐

Indication SHINGLES PROPHYLAXIS

Dose per administration .5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

Name of Medication	ERTAPENEM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEPTICEMIA
Dose per administration	UNKNOWN
Dose unit	mg <input 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 checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
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 type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	UNKNOWN
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 23:37:19

Generated On: 09 Jun 2021 15:12:19

	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 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)		04 APR 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3112262

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:21:04

Generated On: 09 Jun 2021 15:12:19

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3112262

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:12:19

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3112262

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:12:19

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:49:42

Generated On: 09 Jun 2021 15:12:19

SAEID	USA-US062-2021-MRNA-1273-P301000016
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:49:42

Generated On: 09 Jun 2021 15:12:19

SAEID	USA-US062-2021-MRNA-1273-P301000016
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/APR/2021 13:00
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

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:49:42

Generated On: 09 Jun 2021 15:12:19

SAEID	USA-US062-2021-MRNA-1273-P301000016
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/APR/2021 08:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:49:42

Generated On: 09 Jun 2021 15:12:19

SAEID	USA-US062-2021-MRNA-1273-P301000016
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	27/APR/2021 06:22
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

US3112262 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112262

Form: Participant Creation

Generated On: 09 Jun 2021 15:12:19

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:15:36
User entered 'US3112262'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:29:57

US3112262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:24:56
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:01

US3112262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:24:56
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:29:58

US3112262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:24:56
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:01

US3112262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'SCRN'	System	14 Aug 2020 20:03:01

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:29:59

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:29:58
Query 'Per CDM: Please complete this form.'	(b) (4), (b) (6)	21 Aug 2020 18:51:12
answered with 'This is completed.' (Site from DM).		
User entered '70'	(b) (4), (b) (6)	21 Aug 2020 18:51:05
User opened query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 15:57:45

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'YEARS'	System	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered '70'	System	14 Aug 2020 20:03:09

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered 'Male (M)'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered 'l'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:12:19

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:13
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:51:05

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:21
User entered '14 Aug 2020'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:09

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'Aug 2020'	System	14 Aug 2020 20:03:09

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered '2020'	System	14 Aug 2020 20:03:09

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:21
User entered 'Amendment 2 (2)'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:09

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:21
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:09

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:21
User entered empty.	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:09

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:21
User entered empty.	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:09

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:21
User entered 'No (N)'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:09

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:21
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:29:58

US3112262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:12:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'I'	System	14 Aug 2020 20:03:14

US3112262

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:12:19

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:27
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:14

US3112262

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:12:19

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:28:42
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:18:06
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:22:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:22:30
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:12:10
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:55:35

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:23:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:23:53
Data point term sent to Coder	System	25 Sep 2020 21:23:07
User entered 'hypercholesterolemia'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered 'UN UNK 2010'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'Jan 2010'	System	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered '2010'	System	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered empty.	System	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:12:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered empty.	System	25 Sep 2020 21:23:01

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User coded data point as SOC: Surgical and medical procedures, HLG: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary arterial stent insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Sep 2020 05:27:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Sep 2020 05:27:46
Data point term sent to Coder	System	25 Sep 2020 21:24:11
User entered 'coronary artery disease/status post stent'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered 'UN UNK 2002'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered '30 Sep 2003'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:10
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'Jan 2002'	System	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered '2002'	System	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'Sep 2003'	System	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:12:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered '2003'	System	25 Sep 2020 21:23:50

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered '14 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered '11:07'	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered '14 Aug 2020 11:07'	System	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered '170' cm	(b) (4), (b) (6)	21 Aug 2020 18:53:53
DataPoint set to visible.	System	14 Aug 2020 20:03:14

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered '104.5' kg	(b) (4), (b) (6)	21 Aug 2020 18:53:53
DataPoint set to visible.	System	14 Aug 2020 20:03:14

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
Amendment Manager: User entered '36.15917'	System	16 Sep 2020 23:57:44
User entered '36.2'	System	21 Aug 2020 18:53:53
DataPoint set to visible.	System	14 Aug 2020 20:03:14

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'kg/m2'	System	21 Aug 2020 18:53:53
DataPoint set to visible.	System	14 Aug 2020 20:03:14

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
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. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:09:48
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. NOTE: Route is not required.' answered with 'data updated per query request' (Site from DM).	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:52:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:52:36
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. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 19:17:46
User entered '98.1' F	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:52:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:52:36
User entered '67'	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'bpm'	System	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:52:36
User entered '14'	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'breaths/min'	System	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:52:36
User entered '138'	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'mmHg'	System	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:49:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:52:36
User entered '89'	(b) (4), (b) (6)	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User entered 'mmHg'	System	21 Aug 2020 18:53:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 13:07:53

US3112262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53

US3112262

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:50:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:54:18

US3112262

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:50:41
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 03:05:19
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 20:31:15
User entered '14 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:54:18

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Nov 2020 19:49:28
User closed query 'Source indicated production manager at printing company. Verify if there is a presence of risk or not and update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 19:49:27
Query 'Source indicated production manager at printing company. Verify if there is a presence of risk or not and update EDC accordingly. ' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 23:33:48
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:33:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 23:33:41
User opened query 'Source indicated production manager at printing company. Verify if there is a presence of risk or not and update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 16:53:50
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:19:19
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 23:33:41
User entered 'Production Manager at printing company' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 23:33:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered 'I'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:12:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:07:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:52:24
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:52:11

US3112262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:55:29

US3112262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:08
User entered '14 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:55:29

US3112262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:08
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Aug 2020 18:55:29

US3112262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'VISIT1'	System	21 Aug 2020 18:55:29

US3112262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:19

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:32
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:44:21

US3112262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:19

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:32
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:38:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:38:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 18:44:21
User entered '186378' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:44:21

US3112262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:19

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:32
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:44:21

US3112262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:19

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:32
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:51:31

US3112262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:19

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:51:31

US3112262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:19

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:32
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:51:31

US3112262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:19

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:32
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:51:31

US3112262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:32
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:51:31

US3112262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:12:19

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:54:32
User entered 'No (N)'	Karen Mylerberg (b) (4)	25 Sep 2020 21:19:53
Amendment Manager: DataPoint set to visible.	(b) (4)	System 19 Sep 2020 10:21:20
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:22:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '14 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '11:07'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '14 Aug 2020 11:07'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '98.1' F	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '67'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'bpm'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '14'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'breaths/min'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '138'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '89'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '14 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '13:13'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '14 Aug 2020 13:13'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '98.4' F	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '66'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'bpm'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '16'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'breaths/min'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '126'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:21
User entered '78'	(b) (4), (b) (6)	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	21 Aug 2020 18:53:06

US3112262

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:55:02

US3112262

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:29
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:55:02

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:36
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:36
User entered empty.	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:36
User entered empty.	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:36
User entered '14 Aug 2020'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Nov 2020 19:48:37
User closed query 'Source states that injection time is 1240. Please verify actual time and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 19:48:35
Query 'Source states that injection time is 1240. Please verify actual time and update accordingly. ' answered with 'updated' (Site from CRA).	Natalie Moy (b) (4) (b) (4)	04 Nov 2020 21:57:37
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	04 Nov 2020 21:57:31
User entered '12:40' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	04 Nov 2020 21:57:31
User opened query 'Source states that injection time is 1240. Please verify actual time and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 17:05:17
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:02:36
User entered '12:45'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '14 Aug 2020 12:40'	System	04 Nov 2020 21:57:31
User entered '14 Aug 2020 12:45'	System	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:36
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:02:36
User entered 'ONCE'	System	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 20:03:33

US3112262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:54:42

US3112262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:48
User entered '14 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:54:42

US3112262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:48
User entered '11:47'	(b) (4), (b) (6)	21 Aug 2020 18:54:42

US3112262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '14 Aug 2020 11:47'	System	21 Aug 2020 18:54:42

US3112262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:12:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:56
User entered '14 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:54:53

US3112262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 18:54:53

US3112262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:54:53

US3112262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:56
User entered '11:30'	(b) (4), (b) (6)	21 Aug 2020 18:54:53

US3112262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '14 Aug 2020 11:30'	System	21 Aug 2020 18:54:53

US3112262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 18:54:53

US3112262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:56
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:54:53

US3112262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:02:56
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:54:53

US3112262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered empty.	System	21 Aug 2020 18:54:53

US3112262

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:03:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:55:13

US3112262

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	21 Aug 2020 18:55:13

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:15:03', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '3b8f8fb8-a633-4839-9a21-4efe09d3620a' User entered 'Yes (Y)'	System	14 Aug 2020 20:15:26
	System	14 Aug 2020 20:15:26

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:15:09', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '3b8f8fb8-a633-4839-9a21-4efe09d3620a' User entered '98.4'	System	14 Aug 2020 20:15:26
	System	14 Aug 2020 20:15:26

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:15:14', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '3b8f8fb8-a633-4839-9a21-4efe09d3620a'	System	14 Aug 2020 20:15:26
User entered 'No (N)'	System	14 Aug 2020 20:15:26

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:15:21', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '3b8f8fb8-a633-4839-9a21-4efe09d3620a'	System	14 Aug 2020 20:15:26
User entered '14 Aug 2020 13:15'	System	14 Aug 2020 20:15:26

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Aug 2020 13:05'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Aug 2020 15:35'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:02:04', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '19e7f8af-53a3-489b-958f-b31e46655ec2'	System	15 Aug 2020 02:03:40
User entered 'Yes (Y)'	System	15 Aug 2020 02:03:40

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:03:03', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '19e7f8af-53a3-489b-958f-b31e46655ec2'	System	15 Aug 2020 02:03:40
User entered '94.9'	System	15 Aug 2020 02:03:40

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:03:29', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '19e7f8af-53a3-489b-958f-b31e46655ec2'	System	15 Aug 2020 02:03:40
User entered 'No (N)'	System	15 Aug 2020 02:03:40

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:03:37', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '19e7f8af-53a3-489b-958f-b31e46655ec2'	System	15 Aug 2020 02:03:40
User entered '14 Aug 2020 19:03'	System	15 Aug 2020 02:03:40

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Aug 2020 16:30'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 2'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:11:50', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a8e6d06b-0953-4767-884f-06babde3bdc9' User entered 'Yes (Y)'	System	16 Aug 2020 02:12:13
	System	16 Aug 2020 02:12:13

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:11:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a8e6d06b-0953-4767-884f-06babde3bdc9' User entered '96.9'	System	16 Aug 2020 02:12:13
	System	16 Aug 2020 02:12:13

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:12:03', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a8e6d06b-0953-4767-884f-06babde3bdc9' User entered 'No (N)'	System	16 Aug 2020 02:12:13
	System	16 Aug 2020 02:12:13

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:12:09', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a8e6d06b-0953-4767-884f-06babde3bdc9' User entered '15 Aug 2020 19:12'	System	16 Aug 2020 02:12:13
	System	16 Aug 2020 02:12:13

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 3'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:18:08', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd8d12285-bc95-4487-b41d-dfe8b2b0c8f7'	System	17 Aug 2020 03:18:33
User entered 'Yes (Y)'	System	17 Aug 2020 03:18:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:18:13', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd8d12285-bc95-4487-b41d-dfe8b2b0c8f7' User entered '97.9'	System	17 Aug 2020 03:18:33
	System	17 Aug 2020 03:18:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:18:25', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd8d12285-bc95-4487-b41d-dfe8b2b0c8f7'	System	17 Aug 2020 03:18:33
User entered 'No (N)'	System	17 Aug 2020 03:18:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:18:30', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd8d12285-bc95-4487-b41d-dfe8b2b0c8f7'	System	17 Aug 2020 03:18:33
User entered '16 Aug 2020 20:18'	System	17 Aug 2020 03:18:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 4'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:11', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2c600617-533b-4be3-a11b-bb56c62f0d9f' User entered 'Yes (Y)'	System	18 Aug 2020 02:48:28
	System	18 Aug 2020 02:48:28

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:17', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2c600617-533b-4be3-a11b-bb56c62f0d9f' User entered '98.2'	System	18 Aug 2020 02:48:28
	System	18 Aug 2020 02:48:28

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:20', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2c600617-533b-4be3-a11b-bb56c62f0d9f' User entered 'No (N)'	System	18 Aug 2020 02:48:28
	System	18 Aug 2020 02:48:28

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:23', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2c600617-533b-4be3-a11b-bb56c62f0d9f' User entered '17 Aug 2020 19:48'	System	18 Aug 2020 02:48:28
	System	18 Aug 2020 02:48:28

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 5'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T18:59:30', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fa2cc7f1-9921-4346-bb52-9458afc030e0' User entered 'Yes (Y)'	System	19 Aug 2020 01:59:58
	System	19 Aug 2020 01:59:58

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T18:59:36', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fa2cc7f1-9921-4346-bb52-9458afc030e0' User entered '97.7'	System	19 Aug 2020 01:59:58
	System	19 Aug 2020 01:59:58

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T18:59:52', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fa2cc7f1-9921-4346-bb52-9458afc030e0'	System	19 Aug 2020 01:59:58
User entered 'No (N)'	System	19 Aug 2020 01:59:58

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T18:59:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fa2cc7f1-9921-4346-bb52-9458afc030e0' User entered '18 Aug 2020 18:59'	System	19 Aug 2020 01:59:58
	System	19 Aug 2020 01:59:58

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 6'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:28:12', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd67971bc-3038-4043-aaef-b45f3dcca01' User entered 'Yes (Y)'	System	20 Aug 2020 02:28:32
	System	20 Aug 2020 02:28:32

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:28:18', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd67971bc-3038-4043-aaef-b45f3dcca01' User entered '97.7'	System	20 Aug 2020 02:28:32
	System	20 Aug 2020 02:28:32

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:28:23', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd67971bc-3038-4043-aaef-b45f3dcca01' User entered 'No (N)'	System	20 Aug 2020 02:28:32
	System	20 Aug 2020 02:28:32

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:28:30', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd67971bc-3038-4043-aaef-b45f3dcca01' User entered '19 Aug 2020 19:28'	System	20 Aug 2020 02:28:32
	System	20 Aug 2020 02:28:32

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 7'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:04:49', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'eb2c504b-a1c8-45de-b0d6-3ca98bd3c579' User entered 'Yes (Y)'	System	21 Aug 2020 02:05:10
	System	21 Aug 2020 02:05:10

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:04:54', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'eb2c504b-a1c8-45de-b0d6-3ca98bd3c579' User entered '98.5'	System	21 Aug 2020 02:05:10
	System	21 Aug 2020 02:05:10

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:04:59', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'eb2c504b-a1c8-45de-b0d6-3ca98bd3c579' User entered 'No (N)'	System	21 Aug 2020 02:05:10
	System	21 Aug 2020 02:05:10

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:05', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'eb2c504b-a1c8-45de-b0d6-3ca98bd3c579' User entered '20 Aug 2020 19:05'	System	21 Aug 2020 02:05:10
	System	21 Aug 2020 02:05:10

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:15:43', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2779517a-21a0-48cc-a556-546a9f3ead23' User entered 'None (1)'	System	14 Aug 2020 20:16:27
	System	14 Aug 2020 20:16:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:16:01', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2779517a-21a0-48cc-a556-546a9f3ead23' User entered 'No (N)'	System	14 Aug 2020 20:16:27
	System	14 Aug 2020 20:16:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:16:05', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2779517a-21a0-48cc-a556-546a9f3ead23' User entered 'No (N)'	System	14 Aug 2020 20:16:27
	System	14 Aug 2020 20:16:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:16:18', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2779517a-21a0-48cc-a556-546a9f3ead23' User entered 'None (1)'	System	14 Aug 2020 20:16:27
	System	14 Aug 2020 20:16:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:16:24', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2779517a-21a0-48cc-a556-546a9f3ead23' User entered '14 Aug 2020 13:16'	System	14 Aug 2020 20:16:27
	System	14 Aug 2020 20:16:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Aug 2020 13:05'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Aug 2020 15:35'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:03:49', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd32f409b-0011-4aa1-a518-1da5ac6c0dcc'	System	15 Aug 2020 02:06:18
User entered 'None (1)'	System	15 Aug 2020 02:06:18

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd32f409b-0011-4aa1-a518-1da5ac6c0dcc' User entered 'No (N)'	System	15 Aug 2020 02:06:18
	System	15 Aug 2020 02:06:18

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:05', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd32f409b-0011-4aa1-a518-1da5ac6c0dcc' User entered 'No (N)'	System	15 Aug 2020 02:06:18
	System	15 Aug 2020 02:06:18

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:08', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd32f409b-0011-4aa1-a518-1da5ac6c0dcc' User entered 'None (1)'	System	15 Aug 2020 02:06:18
	System	15 Aug 2020 02:06:18

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:15', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd32f409b-0011-4aa1-a518-1da5ac6c0dcc' User entered '14 Aug 2020 19:06'	System	15 Aug 2020 02:06:18
	System	15 Aug 2020 02:06:18

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Aug 2020 16:30'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 2'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:12:22', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0dacf687-e025-46a8-8075-558873e7bf33'	System	16 Aug 2020 02:13:27
User entered 'None (1)'	System	16 Aug 2020 02:13:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:12:48', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0dacf687-e025-46a8-8075-558873e7bf33' User entered 'No (N)'	System	16 Aug 2020 02:13:27
	System	16 Aug 2020 02:13:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:01', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0dacf687-e025-46a8-8075-558873e7bf33' User entered 'No (N)'	System	16 Aug 2020 02:13:27
	System	16 Aug 2020 02:13:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:18', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0dacf687-e025-46a8-8075-558873e7bf33' User entered 'None (1)'	System	16 Aug 2020 02:13:27
	System	16 Aug 2020 02:13:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:22', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0dacf687-e025-46a8-8075-558873e7bf33' User entered '15 Aug 2020 19:13'	System	16 Aug 2020 02:13:27
	System	16 Aug 2020 02:13:27

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 3'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:18:38', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '913c103f-3cd8-43bc-a531-201664b8e8a7' User entered 'None (1)'	System	17 Aug 2020 03:19:08
	System	17 Aug 2020 03:19:08

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:18:42', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '913c103f-3cd8-43bc-a531-201664b8e8a7' User entered 'No (N)'	System	17 Aug 2020 03:19:08
	System	17 Aug 2020 03:19:08

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:18:46', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '913c103f-3cd8-43bc-a531-201664b8e8a7' User entered 'No (N)'	System	17 Aug 2020 03:19:08
	System	17 Aug 2020 03:19:08

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:18:59', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '913c103f-3cd8-43bc-a531-201664b8e8a7' User entered 'None (1)'	System	17 Aug 2020 03:19:08
	System	17 Aug 2020 03:19:08

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:19:03', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '913c103f-3cd8-43bc-a531-201664b8e8a7' User entered '16 Aug 2020 20:19'	System	17 Aug 2020 03:19:08
	System	17 Aug 2020 03:19:08

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 4'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:28', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '511db2d4-e3bb-4726-9cb0-c80373bc987b' User entered 'None (1)'	System	18 Aug 2020 02:48:44
	System	18 Aug 2020 02:48:44

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:31', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '511db2d4-e3bb-4726-9cb0-c80373bc987b' User entered 'No (N)'	System	18 Aug 2020 02:48:44
	System	18 Aug 2020 02:48:44

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:34', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '511db2d4-e3bb-4726-9cb0-c80373bc987b' User entered 'No (N)'	System	18 Aug 2020 02:48:44
	System	18 Aug 2020 02:48:44

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:38', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '511db2d4-e3bb-4726-9cb0-c80373bc987b' User entered 'None (1)'	System	18 Aug 2020 02:48:44
	System	18 Aug 2020 02:48:44

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:42', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '511db2d4-e3bb-4726-9cb0-c80373bc987b' User entered '17 Aug 2020 19:48'	System	18 Aug 2020 02:48:44
	System	18 Aug 2020 02:48:44

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 5'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:00:15', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41e03781-fa51-4a2a-a9de-2f9481dfdd15'	System	19 Aug 2020 02:00:49
User entered 'None (1)'	System	19 Aug 2020 02:00:49

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:00:19', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41e03781-fa51-4a2a-a9de-2f9481dfdd15'	System	19 Aug 2020 02:00:49
User entered 'No (N)'	System	19 Aug 2020 02:00:49

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:00:22', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41e03781-fa51-4a2a-a9de-2f9481dfdd15'	System	19 Aug 2020 02:00:49
User entered 'No (N)'	System	19 Aug 2020 02:00:49

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:00:37', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41e03781-fa51-4a2a-a9de-2f9481dfdd15'	System	19 Aug 2020 02:00:49
User entered 'None (1)'	System	19 Aug 2020 02:00:49

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:00:45', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41e03781-fa51-4a2a-a9de-2f9481dfdd15'	System	19 Aug 2020 02:00:49
User entered '18 Aug 2020 19:00'	System	19 Aug 2020 02:00:49

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 6'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:28:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8b6746f2-2f23-4f6b-82e2-6118d5a797af'	System	20 Aug 2020 02:28:59
User entered 'None (1)'	System	20 Aug 2020 02:28:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:28:39', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8b6746f2-2f23-4f6b-82e2-6118d5a797af'	System	20 Aug 2020 02:28:59
User entered 'No (N)'	System	20 Aug 2020 02:28:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:28:42', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8b6746f2-2f23-4f6b-82e2-6118d5a797af'	System	20 Aug 2020 02:28:59
User entered 'No (N)'	System	20 Aug 2020 02:28:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:28:45', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8b6746f2-2f23-4f6b-82e2-6118d5a797af'	System	20 Aug 2020 02:28:59
User entered 'None (1)'	System	20 Aug 2020 02:28:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:28:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8b6746f2-2f23-4f6b-82e2-6118d5a797af' User entered '19 Aug 2020 19:28'	System	20 Aug 2020 02:28:59
	System	20 Aug 2020 02:28:59

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 7'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:12', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff61258d-c52d-48d3-8860-44dc8ca45564'	System	21 Aug 2020 02:05:34
User entered 'None (1)'	System	21 Aug 2020 02:05:34

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:15', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff61258d-c52d-48d3-8860-44dc8ca45564' User entered 'No (N)'	System	21 Aug 2020 02:05:34
	System	21 Aug 2020 02:05:34

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:18', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff61258d-c52d-48d3-8860-44dc8ca45564' User entered 'No (N)'	System	21 Aug 2020 02:05:34
	System	21 Aug 2020 02:05:34

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:22', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff61258d-c52d-48d3-8860-44dc8ca45564'	System	21 Aug 2020 02:05:34
User entered 'None (1)'	System	21 Aug 2020 02:05:34

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:30', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff61258d-c52d-48d3-8860-44dc8ca45564'	System	21 Aug 2020 02:05:34
User entered '20 Aug 2020 19:05'	System	21 Aug 2020 02:05:34

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:16:41', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a7f47472-d6d6-4c16-8bdc-d4ed0298435c' User entered 'None (0)'	System	14 Aug 2020 20:17:25
	System	14 Aug 2020 20:17:25

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:16:49', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a7f47472-d6d6-4c16-8bdc-d4ed0298435c' User entered 'None (0)'	System	14 Aug 2020 20:17:25
	System	14 Aug 2020 20:17:25

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:16:56', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a7f47472-d6d6-4c16-8bdc-d4ed0298435c' User entered 'None (0)'	System	14 Aug 2020 20:17:25
	System	14 Aug 2020 20:17:25

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:17:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a7f47472-d6d6-4c16-8bdc-d4ed0298435c' User entered 'None (0)'	System	14 Aug 2020 20:17:25
	System	14 Aug 2020 20:17:25

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:17:06', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a7f47472-d6d6-4c16-8bdc-d4ed0298435c' User entered 'None (0)'	System	14 Aug 2020 20:17:25
	System	14 Aug 2020 20:17:25

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:17:09', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a7f47472-d6d6-4c16-8bdc-d4ed0298435c' User entered 'None (0)'	System	14 Aug 2020 20:17:25
	System	14 Aug 2020 20:17:25

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:17:16', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a7f47472-d6d6-4c16-8bdc-d4ed0298435c' User entered 'No (N)'	System	14 Aug 2020 20:17:25
	System	14 Aug 2020 20:17:25

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T13:17:23', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a7f47472-d6d6-4c16-8bdc-d4ed0298435c' User entered '14 Aug 2020 13:17'	System	14 Aug 2020 20:17:25
	System	14 Aug 2020 20:17:25

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Aug 2020 13:05'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Aug 2020 15:35'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:29', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7d8ea0d-7eb7-402c-92dc-109ec0a5ad9e' User entered 'None (0)'	System	15 Aug 2020 02:07:02
	System	15 Aug 2020 02:07:02

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:37', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7d8ea0d-7eb7-402c-92dc-109ec0a5ad9e' User entered 'None (0)'	System	15 Aug 2020 02:07:02
	System	15 Aug 2020 02:07:02

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:41', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7d8ea0d-7eb7-402c-92dc-109ec0a5ad9e' User entered 'None (0)'	System	15 Aug 2020 02:07:02
	System	15 Aug 2020 02:07:02

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:44', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7d8ea0d-7eb7-402c-92dc-109ec0a5ad9e' User entered 'None (0)'	System	15 Aug 2020 02:07:02
	System	15 Aug 2020 02:07:02

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:47', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7d8ea0d-7eb7-402c-92dc-109ec0a5ad9e' User entered 'None (0)'	System	15 Aug 2020 02:07:02
	System	15 Aug 2020 02:07:02

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:50', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7d8ea0d-7eb7-402c-92dc-109ec0a5ad9e' User entered 'None (0)'	System	15 Aug 2020 02:07:02
	System	15 Aug 2020 02:07:02

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:53', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7d8ea0d-7eb7-402c-92dc-109ec0a5ad9e' User entered 'No (N)'	System	15 Aug 2020 02:07:02
	System	15 Aug 2020 02:07:02

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-14T19:06:59', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7d8ea0d-7eb7-402c-92dc-109ec0a5ad9e' User entered '14 Aug 2020 19:06'	System	15 Aug 2020 02:07:02
	System	15 Aug 2020 02:07:02

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Aug 2020 16:30'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 2'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:32', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '7f45ddf7-3087-4a39-8617-db48856daa87' User entered 'None (0)'	System	16 Aug 2020 02:14:03
	System	16 Aug 2020 02:14:03

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:36', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '7f45ddf7-3087-4a39-8617-db48856daa87' User entered 'None (0)'	System	16 Aug 2020 02:14:03
	System	16 Aug 2020 02:14:03

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:39', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '7f45ddf7-3087-4a39-8617-db48856daa87' User entered 'None (0)'	System	16 Aug 2020 02:14:03
	System	16 Aug 2020 02:14:03

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:43', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '7f45ddf7-3087-4a39-8617-db48856daa87' User entered 'None (0)'	System	16 Aug 2020 02:14:03
	System	16 Aug 2020 02:14:03

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:46', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '7f45ddf7-3087-4a39-8617-db48856daa87' User entered 'None (0)'	System	16 Aug 2020 02:14:03
	System	16 Aug 2020 02:14:03

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:48', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '7f45ddf7-3087-4a39-8617-db48856daa87' User entered 'None (0)'	System	16 Aug 2020 02:14:03
	System	16 Aug 2020 02:14:03

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:13:53', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '7f45ddf7-3087-4a39-8617-db48856daa87' User entered 'No (N)'	System	16 Aug 2020 02:14:03
	System	16 Aug 2020 02:14:03

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-15T19:14:02', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '7f45ddf7-3087-4a39-8617-db48856daa87' User entered '15 Aug 2020 19:14'	System	16 Aug 2020 02:14:03
	System	16 Aug 2020 02:14:03

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 3'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:19:10', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0ee6d9d3-9510-4c61-986f-d1f4a4b884cf' User entered 'None (0)'	System	17 Aug 2020 03:19:38
	System	17 Aug 2020 03:19:38

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:19:14', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0ee6d9d3-9510-4c61-986f-d1f4a4b884cf' User entered 'None (0)'	System	17 Aug 2020 03:19:38
	System	17 Aug 2020 03:19:38

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:19:18', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0ee6d9d3-9510-4c61-986f-d1f4a4b884cf' User entered 'None (0)'	System	17 Aug 2020 03:19:38
	System	17 Aug 2020 03:19:38

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:19:22', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0ee6d9d3-9510-4c61-986f-d1f4a4b884cf' User entered 'None (0)'	System	17 Aug 2020 03:19:38
	System	17 Aug 2020 03:19:38

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:19:25', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0ee6d9d3-9510-4c61-986f-d1f4a4b884cf' User entered 'None (0)'	System	17 Aug 2020 03:19:38
	System	17 Aug 2020 03:19:38

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:19:27', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0ee6d9d3-9510-4c61-986f-d1f4a4b884cf' User entered 'None (0)'	System	17 Aug 2020 03:19:38
	System	17 Aug 2020 03:19:38

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:19:31', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0ee6d9d3-9510-4c61-986f-d1f4a4b884cf' User entered 'No (N)'	System	17 Aug 2020 03:19:38
	System	17 Aug 2020 03:19:38

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-16T20:19:36', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0ee6d9d3-9510-4c61-986f-d1f4a4b884cf' User entered '16 Aug 2020 20:19'	System	17 Aug 2020 03:19:38
	System	17 Aug 2020 03:19:38

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 4'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:47', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41730a22-0ba1-4120-9610-5f6930d479e0' User entered 'None (0)'	System	18 Aug 2020 02:49:09
	System	18 Aug 2020 02:49:09

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:50', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41730a22-0ba1-4120-9610-5f6930d479e0' User entered 'None (0)'	System	18 Aug 2020 02:49:09
	System	18 Aug 2020 02:49:09

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:52', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41730a22-0ba1-4120-9610-5f6930d479e0' User entered 'None (0)'	System	18 Aug 2020 02:49:09
	System	18 Aug 2020 02:49:09

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:55', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41730a22-0ba1-4120-9610-5f6930d479e0' User entered 'None (0)'	System	18 Aug 2020 02:49:09
	System	18 Aug 2020 02:49:09

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41730a22-0ba1-4120-9610-5f6930d479e0' User entered 'None (0)'	System	18 Aug 2020 02:49:09
	System	18 Aug 2020 02:49:09

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:48:59', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41730a22-0ba1-4120-9610-5f6930d479e0' User entered 'None (0)'	System	18 Aug 2020 02:49:09
	System	18 Aug 2020 02:49:09

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:49:03', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41730a22-0ba1-4120-9610-5f6930d479e0' User entered 'No (N)'	System	18 Aug 2020 02:49:09
	System	18 Aug 2020 02:49:09

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-17T19:49:06', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '41730a22-0ba1-4120-9610-5f6930d479e0' User entered '17 Aug 2020 19:49'	System	18 Aug 2020 02:49:09
	System	18 Aug 2020 02:49:09

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 5'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:01:20', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '785abf15-4187-4dab-8a83-f9e3287dd9c2' User entered 'None (0)'	System	19 Aug 2020 02:02:05
	System	19 Aug 2020 02:02:05

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:01:32', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '785abf15-4187-4dab-8a83-f9e3287dd9c2' User entered 'None (0)'	System	19 Aug 2020 02:02:05
	System	19 Aug 2020 02:02:05

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:01:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '785abf15-4187-4dab-8a83-f9e3287dd9c2' User entered 'None (0)'	System	19 Aug 2020 02:02:05
	System	19 Aug 2020 02:02:05

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:01:40', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '785abf15-4187-4dab-8a83-f9e3287dd9c2' User entered 'None (0)'	System	19 Aug 2020 02:02:05
	System	19 Aug 2020 02:02:05

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:01:45', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '785abf15-4187-4dab-8a83-f9e3287dd9c2' User entered 'None (0)'	System	19 Aug 2020 02:02:05
	System	19 Aug 2020 02:02:05

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:01:51', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '785abf15-4187-4dab-8a83-f9e3287dd9c2' User entered 'None (0)'	System	19 Aug 2020 02:02:05
	System	19 Aug 2020 02:02:05

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:01:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '785abf15-4187-4dab-8a83-f9e3287dd9c2' User entered 'No (N)'	System	19 Aug 2020 02:02:05
	System	19 Aug 2020 02:02:05

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-18T19:02:02', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '785abf15-4187-4dab-8a83-f9e3287dd9c2'	System	19 Aug 2020 02:02:05
User entered '18 Aug 2020 19:02'	System	19 Aug 2020 02:02:05

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 6'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:29:01', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2052b846-ecea-4a5b-9fcf-c4a9d8c5fe57' User entered 'None (0)'	System	20 Aug 2020 02:29:32
	System	20 Aug 2020 02:29:32

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:29:04', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2052b846-ecea-4a5b-9fcf-c4a9d8c5fe57' User entered 'None (0)'	System	20 Aug 2020 02:29:32
	System	20 Aug 2020 02:29:32

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:29:07', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2052b846-ecea-4a5b-9fcf-c4a9d8c5fe57' User entered 'None (0)'	System	20 Aug 2020 02:29:32
	System	20 Aug 2020 02:29:32

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:29:14', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2052b846-ecea-4a5b-9fcf-c4a9d8c5fe57' User entered 'None (0)'	System	20 Aug 2020 02:29:32
	System	20 Aug 2020 02:29:32

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:29:17', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2052b846-ecea-4a5b-9fcf-c4a9d8c5fe57' User entered 'None (0)'	System	20 Aug 2020 02:29:32
	System	20 Aug 2020 02:29:32

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:29:19', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2052b846-ecea-4a5b-9fcf-c4a9d8c5fe57' User entered 'None (0)'	System	20 Aug 2020 02:29:32
	System	20 Aug 2020 02:29:32

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:29:23', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2052b846-ecea-4a5b-9fcf-c4a9d8c5fe57'	System	20 Aug 2020 02:29:32
User entered 'No (N)'	System	20 Aug 2020 02:29:32

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-19T19:29:29', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2052b846-ecea-4a5b-9fcf-c4a9d8c5fe57' User entered '19 Aug 2020 19:29'	System	20 Aug 2020 02:29:32
	System	20 Aug 2020 02:29:32

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 7'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:36', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '433938ea-78d7-4e17-af9f-d852b0d1e7e2' User entered 'None (0)'	System	21 Aug 2020 02:06:01
	System	21 Aug 2020 02:06:01

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:38', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '433938ea-78d7-4e17-af9f-d852b0d1e7e2' User entered 'None (0)'	System	21 Aug 2020 02:06:01
	System	21 Aug 2020 02:06:01

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:41', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '433938ea-78d7-4e17-af9f-d852b0d1e7e2' User entered 'None (0)'	System	21 Aug 2020 02:06:01
	System	21 Aug 2020 02:06:01

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:43', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '433938ea-78d7-4e17-af9f-d852b0d1e7e2' User entered 'None (0)'	System	21 Aug 2020 02:06:01
	System	21 Aug 2020 02:06:01

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:46', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '433938ea-78d7-4e17-af9f-d852b0d1e7e2' User entered 'None (0)'	System	21 Aug 2020 02:06:01
	System	21 Aug 2020 02:06:01

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:49', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '433938ea-78d7-4e17-af9f-d852b0d1e7e2' User entered 'None (0)'	System	21 Aug 2020 02:06:01
	System	21 Aug 2020 02:06:01

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:53', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '433938ea-78d7-4e17-af9f-d852b0d1e7e2' User entered 'No (N)'	System	21 Aug 2020 02:06:01
	System	21 Aug 2020 02:06:01

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-08-20T19:05:58', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '433938ea-78d7-4e17-af9f-d852b0d1e7e2' User entered '20 Aug 2020 19:05'	System	21 Aug 2020 02:06:01
	System	21 Aug 2020 02:06:01

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:03:33

US3112262

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:09:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 21:19:09

US3112262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:09:06
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 21:19:09

US3112262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:09:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Aug 2020 21:19:09

US3112262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:09:06
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 21:19:09

US3112262

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:09:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 21:19:14

US3112262

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	21 Aug 2020 21:19:14

US3112262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:10:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 00:19:05

US3112262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:10:46
User entered '28 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 00:19:05

US3112262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:10:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Aug 2020 00:19:05

US3112262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:10:46
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 00:19:05

US3112262

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:10:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 00:19:10

US3112262

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	29 Aug 2020 00:19:10

US3112262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:11:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:57:13

US3112262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:11:04
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:57:13

US3112262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:11:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 20:57:13

US3112262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:11:04
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:57:13

US3112262

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:11:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:57:18

US3112262

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	04 Sep 2020 20:57:18

US3112262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:44:52
User closed query 'Per CDM: For Visit 2, "Was this visit performed?" is recorded as 'Yes'. Please review and update vital sign dosing as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:18:15
Query 'Per CDM: For Visit 2, "Was this visit performed?" is recorded as 'Yes'. Please review and update vital sign dosing as appropriate.' answered with 'form updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:25:49
User opened query 'Per CDM: For Visit 2, "Was this visit performed?" is recorded as 'Yes'. Please review and update vital sign dosing as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 16:34:34
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:15

US3112262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:44:52
User entered '11 Sep 2020'	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:15

US3112262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:44:52
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:15

US3112262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'VISIT2'	System	11 Sep 2020 20:31:15

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '11 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '11:49'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '11 Sep 2020 11:49'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '98.4' F	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '64'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'bpm'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '16'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'breaths/min'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '121'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '80'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '11 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '14:01'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '11 Sep 2020 14:01'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '98.2' F	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '66'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'bpm'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '18'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'breaths/min'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '136'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:36
User entered '84'	(b) (4), (b) (6)	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	18 Sep 2020 21:03:54

US3112262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	02 Oct 2020 20:03:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:04:02

US3112262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:46:52
User entered '11 Sep 2020' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	02 Oct 2020 20:03:42
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:04:02

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:12
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:12
User entered empty.	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:12
User entered empty.	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:12
User entered '11 Sep 2020'	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:12
User entered '13:22'	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '11 Sep 2020 13:22'	System	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:12
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 20:47:12
User entered 'ONCE'	System	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 20:31:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:04:17

US3112262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:26
User entered '11 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 21:04:17

US3112262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:26
User entered '12:35'	(b) (4), (b) (6)	18 Sep 2020 21:04:17

US3112262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '11 Sep 2020 12:35'	System	18 Sep 2020 21:04:17

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:12:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:36
User entered '11 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 21:04:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	18 Sep 2020 21:04:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:04:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:36
User entered '12:00'	(b) (4), (b) (6)	18 Sep 2020 21:04:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:12:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '11 Sep 2020 12:00'	System	18 Sep 2020 21:04:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	18 Sep 2020 21:04:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:36
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 21:04:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:36
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:04:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:12:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered empty.	System	18 Sep 2020 21:04:33

US3112262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:47:46
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Sep 2020 20:31:39

US3112262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	11 Sep 2020 20:31:39

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '11 Sep 2020 13:42'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '11 Sep 2020 16:12'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:01:46', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '5c37c516-9424-47ea-8ae3-501aa5af14a3' User entered 'Yes (Y)'	System	12 Sep 2020 01:02:11
	System	12 Sep 2020 01:02:11

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:01:56', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '5c37c516-9424-47ea-8ae3-501aa5af14a3' User entered '98.1'	System	12 Sep 2020 01:02:11
	System	12 Sep 2020 01:02:11

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:02:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '5c37c516-9424-47ea-8ae3-501aa5af14a3'	System	12 Sep 2020 01:02:11
User entered 'No (N)'	System	12 Sep 2020 01:02:11

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:02:07', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '5c37c516-9424-47ea-8ae3-501aa5af14a3' User entered '11 Sep 2020 18:02'	System	12 Sep 2020 01:02:11
	System	12 Sep 2020 01:02:11

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '11 Sep 2020 17:07'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 2'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:39:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'c11ac641-96fc-4cd4-a021-a8b87f7a3106' User entered 'Yes (Y)'	System	13 Sep 2020 01:40:28
	System	13 Sep 2020 01:40:28

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:39:47', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'c11ac641-96fc-4cd4-a021-a8b87f7a3106' User entered '98.9'	System	13 Sep 2020 01:40:28
	System	13 Sep 2020 01:40:28

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:40:04', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'c11ac641-96fc-4cd4-a021-a8b87f7a3106'	System	13 Sep 2020 01:40:28
User entered 'Yes (Y)'	System	13 Sep 2020 01:40:28

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 12:17:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:40:11', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'c11ac641-96fc-4cd4-a021-a8b87f7a3106'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:25:18
User entered '1'	System	13 Sep 2020 01:40:28
	System	13 Sep 2020 01:40:28
	System	13 Sep 2020 01:40:28

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:40:11', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'c11ac641-96fc-4cd4-a021-a8b87f7a3106' User entered '0'	System	13 Sep 2020 01:40:28
	System	13 Sep 2020 01:40:28

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:40:26', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'c11ac641-96fc-4cd4-a021-a8b87f7a3106'	System	13 Sep 2020 01:40:28
User entered '12 Sep 2020 18:40'	System	13 Sep 2020 01:40:28

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 3'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:45:44', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8fb7a796-935b-4be4-8d22-d16ef904dd4c' User entered 'Yes (Y)'	System	14 Sep 2020 02:46:05
	System	14 Sep 2020 02:46:05

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:45:51', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8fb7a796-935b-4be4-8d22-d16ef904dd4c' User entered '99.6'	System	14 Sep 2020 02:46:05
	System	14 Sep 2020 02:46:05

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:45:55', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8fb7a796-935b-4be4-8d22-d16ef904dd4c' User entered 'No (N)'	System	14 Sep 2020 02:46:05
	System	14 Sep 2020 02:46:05

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:46:01', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8fb7a796-935b-4be4-8d22-d16ef904dd4c' User entered '13 Sep 2020 19:46'	System	14 Sep 2020 02:46:05
	System	14 Sep 2020 02:46:05

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 4'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:06:12', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a0ccef29-c404-4be4-9a8c-b80f6c52f874' User entered 'Yes (Y)'	System	15 Sep 2020 05:06:40
	System	15 Sep 2020 05:06:40

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:06:25', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a0ccef29-c404-4be4-9a8c-b80f6c52f874' User entered '97.8'	System	15 Sep 2020 05:06:40
	System	15 Sep 2020 05:06:40

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:06:32', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a0cce29-c404-4be4-9a8c-b80f6c52f874'	System	15 Sep 2020 05:06:40
User entered 'No (N)'	System	15 Sep 2020 05:06:40

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:06:37', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a0ccef29-c404-4be4-9a8c-b80f6c52f874' User entered '14 Sep 2020 22:06'	System	15 Sep 2020 05:06:40
	System	15 Sep 2020 05:06:40

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 5'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:16:29', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '284bf159-d9a8-4b60-8388-1be4221cffa6'	System	16 Sep 2020 03:16:49
User entered 'Yes (Y)'	System	16 Sep 2020 03:16:49

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:16:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '284bf159-d9a8-4b60-8388-1be4221cffa6' User entered '98.0'	System	16 Sep 2020 03:16:49
	System	16 Sep 2020 03:16:49

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:16:40', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '284bf159-d9a8-4b60-8388-1be4221cffa6'	System	16 Sep 2020 03:16:49
User entered 'No (N)'	System	16 Sep 2020 03:16:49

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:16:46', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '284bf159-d9a8-4b60-8388-1be4221cffa6'	System	16 Sep 2020 03:16:49
User entered '15 Sep 2020 20:16'	System	16 Sep 2020 03:16:49

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 6'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:35:16', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '6511ed50-298c-4800-9005-ec228c87c013' User entered 'Yes (Y)'	System	17 Sep 2020 02:35:35
	System	17 Sep 2020 02:35:35

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:35:22', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '6511ed50-298c-4800-9005-ec228c87c013' User entered '97.6'	System	17 Sep 2020 02:35:35
	System	17 Sep 2020 02:35:35

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:35:25', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '6511ed50-298c-4800-9005-ec228c87c013' User entered 'No (N)'	System	17 Sep 2020 02:35:35
	System	17 Sep 2020 02:35:35

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:35:29', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '6511ed50-298c-4800-9005-ec228c87c013' User entered '16 Sep 2020 19:35'	System	17 Sep 2020 02:35:35
	System	17 Sep 2020 02:35:35

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 7'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:25:17', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b6572fe6-dff4-4f46-a532-5278101290ab' User entered 'Yes (Y)'	System	18 Sep 2020 02:26:17
	System	18 Sep 2020 02:26:17

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:08', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b6572fe6-dff4-4f46-a532-5278101290ab' User entered '98.3'	System	18 Sep 2020 02:26:17
	System	18 Sep 2020 02:26:17

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:11', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b6572fe6-dff4-4f46-a532-5278101290ab' User entered 'No (N)'	System	18 Sep 2020 02:26:17
	System	18 Sep 2020 02:26:17

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:16', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b6572fe6-dff4-4f46-a532-5278101290ab' User entered '17 Sep 2020 19:26'	System	18 Sep 2020 02:26:17
	System	18 Sep 2020 02:26:17

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '11 Sep 2020 13:42'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '11 Sep 2020 16:12'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:02:17', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9ecc2ccc-56d1-455b-9cc2-5a63b98a93fe' User entered 'None (1)'	System	12 Sep 2020 01:03:00
	System	12 Sep 2020 01:03:00

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:02:42', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9ecc2ccc-56d1-455b-9cc2-5a63b98a93fe' User entered 'No (N)'	System	12 Sep 2020 01:03:00
	System	12 Sep 2020 01:03:00

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:02:47', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9ecc2ccc-56d1-455b-9cc2-5a63b98a93fe' User entered 'No (N)'	System	12 Sep 2020 01:03:00
	System	12 Sep 2020 01:03:00

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:02:52', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9ecc2ccc-56d1-455b-9cc2-5a63b98a93fe' User entered 'None (1)'	System	12 Sep 2020 01:03:00
	System	12 Sep 2020 01:03:00

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:02:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9ecc2ccc-56d1-455b-9cc2-5a63b98a93fe' User entered '11 Sep 2020 18:02'	System	12 Sep 2020 01:03:00
	System	12 Sep 2020 01:03:00

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '11 Sep 2020 17:07'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 2'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:40:55', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '681c3798-80d3-45d6-b72d-623824f0ee3c' User entered 'None (1)'	System	13 Sep 2020 01:42:37
	System	13 Sep 2020 01:42:37

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:41:25', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '681c3798-80d3-45d6-b72d-623824f0ee3c' User entered 'No (N)'	System	13 Sep 2020 01:42:37
	System	13 Sep 2020 01:42:37

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:41:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '681c3798-80d3-45d6-b72d-623824f0ee3c' User entered 'No (N)'	System	13 Sep 2020 01:42:37
	System	13 Sep 2020 01:42:37

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:41:47', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '681c3798-80d3-45d6-b72d-623824f0ee3c' User entered 'None (1)'	System	13 Sep 2020 01:42:37
	System	13 Sep 2020 01:42:37

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:42:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '681c3798-80d3-45d6-b72d-623824f0ee3c' User entered '12 Sep 2020 18:42'	System	13 Sep 2020 01:42:37
	System	13 Sep 2020 01:42:37

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 3'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:46:16', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9a918a8b-6600-4144-b5b4-eaf1a3e58a19' User entered 'None (1)'	System	14 Sep 2020 02:46:58
	System	14 Sep 2020 02:46:58

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:46:20', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9a918a8b-6600-4144-b5b4-eaf1a3e58a19' User entered 'No (N)'	System	14 Sep 2020 02:46:58
	System	14 Sep 2020 02:46:58

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:46:23', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9a918a8b-6600-4144-b5b4-eaf1a3e58a19' User entered 'No (N)'	System	14 Sep 2020 02:46:58
	System	14 Sep 2020 02:46:58

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:46:48', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9a918a8b-6600-4144-b5b4-eaf1a3e58a19' User entered 'None (1)'	System	14 Sep 2020 02:46:58
	System	14 Sep 2020 02:46:58

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:46:54', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9a918a8b-6600-4144-b5b4-eaf1a3e58a19' User entered '13 Sep 2020 19:46'	System	14 Sep 2020 02:46:58
	System	14 Sep 2020 02:46:58

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 4'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:06:42', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '664f69e9-9391-4de0-a762-7dedb0e497ce' User entered 'None (1)'	System	15 Sep 2020 05:07:04
	System	15 Sep 2020 05:07:04

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:06:45', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '664f69e9-9391-4de0-a762-7dedb0e497ce' User entered 'No (N)'	System	15 Sep 2020 05:07:04
	System	15 Sep 2020 05:07:04

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:06:48', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '664f69e9-9391-4de0-a762-7dedb0e497ce' User entered 'No (N)'	System	15 Sep 2020 05:07:04
	System	15 Sep 2020 05:07:04

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:06:52', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '664f69e9-9391-4de0-a762-7dedb0e497ce' User entered 'None (1)'	System	15 Sep 2020 05:07:04
	System	15 Sep 2020 05:07:04

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '664f69e9-9391-4de0-a762-7dedb0e497ce' User entered '14 Sep 2020 22:07'	System	15 Sep 2020 05:07:04
	System	15 Sep 2020 05:07:04

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 5'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:16:51', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f40c9453-b528-42a5-bb7b-255abdb68a1b' User entered 'None (1)'	System	16 Sep 2020 03:17:27
	System	16 Sep 2020 03:17:27

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:16:54', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f40c9453-b528-42a5-bb7b-255abdb68a1b' User entered 'No (N)'	System	16 Sep 2020 03:17:27
	System	16 Sep 2020 03:17:27

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:16:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f40c9453-b528-42a5-bb7b-255abdb68a1b' User entered 'No (N)'	System	16 Sep 2020 03:17:27
	System	16 Sep 2020 03:17:27

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f40c9453-b528-42a5-bb7b-255abdb68a1b' User entered 'None (1)'	System	16 Sep 2020 03:17:27
	System	16 Sep 2020 03:17:27

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:22', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f40c9453-b528-42a5-bb7b-255abdb68a1b' User entered '15 Sep 2020 20:17'	System	16 Sep 2020 03:17:27
	System	16 Sep 2020 03:17:27

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 6'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:35:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd8e319fd-0416-4098-95a7-ffcc19e63ebb' User entered 'None (1)'	System	17 Sep 2020 02:36:15
	System	17 Sep 2020 02:36:15

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:35:50', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd8e319fd-0416-4098-95a7-ffcc19e63ebb' User entered 'No (N)'	System	17 Sep 2020 02:36:15
	System	17 Sep 2020 02:36:15

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:35:53', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd8e319fd-0416-4098-95a7-ffcc19e63ebb' User entered 'No (N)'	System	17 Sep 2020 02:36:15
	System	17 Sep 2020 02:36:15

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:07', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd8e319fd-0416-4098-95a7-ffcc19e63ebb'	System	17 Sep 2020 02:36:15
User entered 'None (1)'	System	17 Sep 2020 02:36:15

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:12', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd8e319fd-0416-4098-95a7-ffcc19e63ebb' User entered '16 Sep 2020 19:36'	System	17 Sep 2020 02:36:15
	System	17 Sep 2020 02:36:15

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 7'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:22', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '172ad56e-c8e6-45fd-a310-e6a2e7e72c2d' User entered 'None (1)'	System	18 Sep 2020 02:26:49
	System	18 Sep 2020 02:26:49

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:29', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '172ad56e-c8e6-45fd-a310-e6a2e7e72c2d' User entered 'No (N)'	System	18 Sep 2020 02:26:49
	System	18 Sep 2020 02:26:49

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:32', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '172ad56e-c8e6-45fd-a310-e6a2e7e72c2d' User entered 'No (N)'	System	18 Sep 2020 02:26:49
	System	18 Sep 2020 02:26:49

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:38', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '172ad56e-c8e6-45fd-a310-e6a2e7e72c2d' User entered 'None (1)'	System	18 Sep 2020 02:26:49
	System	18 Sep 2020 02:26:49

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:44', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '172ad56e-c8e6-45fd-a310-e6a2e7e72c2d' User entered '17 Sep 2020 19:26'	System	18 Sep 2020 02:26:49
	System	18 Sep 2020 02:26:49

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '11 Sep 2020 13:42'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '11 Sep 2020 16:12'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:03:03', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e232cb54-0c3f-44b8-90da-ef400dd639a1' User entered 'None (0)'	System	12 Sep 2020 01:03:38
	System	12 Sep 2020 01:03:38

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:03:06', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e232cb54-0c3f-44b8-90da-ef400dd639a1' User entered 'None (0)'	System	12 Sep 2020 01:03:38
	System	12 Sep 2020 01:03:38

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:03:09', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e232cb54-0c3f-44b8-90da-ef400dd639a1' User entered 'None (0)'	System	12 Sep 2020 01:03:38
	System	12 Sep 2020 01:03:38

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:03:11', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e232cb54-0c3f-44b8-90da-ef400dd639a1' User entered 'None (0)'	System	12 Sep 2020 01:03:38
	System	12 Sep 2020 01:03:38

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:03:14', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e232cb54-0c3f-44b8-90da-ef400dd639a1' User entered 'None (0)'	System	12 Sep 2020 01:03:38
	System	12 Sep 2020 01:03:38

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:03:17', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e232cb54-0c3f-44b8-90da-ef400dd639a1' User entered 'None (0)'	System	12 Sep 2020 01:03:38
	System	12 Sep 2020 01:03:38

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:03:21', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e232cb54-0c3f-44b8-90da-ef400dd639a1' User entered 'No (N)'	System	12 Sep 2020 01:03:38
	System	12 Sep 2020 01:03:38

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-11T18:03:27', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e232cb54-0c3f-44b8-90da-ef400dd639a1' User entered '11 Sep 2020 18:03'	System	12 Sep 2020 01:03:38
	System	12 Sep 2020 01:03:38

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '11 Sep 2020 17:07'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 2'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:48:38', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4987b96a-8b24-4f4d-9865-055278096c14'	System	13 Sep 2020 01:55:03
User entered 'No interference with activity (1)'	System	13 Sep 2020 01:55:03

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:48:58', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4987b96a-8b24-4f4d-9865-055278096c14'	System	13 Sep 2020 01:55:03
User entered 'Significant; prevents daily activity (3)'	System	13 Sep 2020 01:55:03

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:50:40', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4987b96a-8b24-4f4d-9865-055278096c14'	System	13 Sep 2020 01:55:03
User entered 'Some interference with activity (2)'	System	13 Sep 2020 01:55:03

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:51:02', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4987b96a-8b24-4f4d-9865-055278096c14'	System	13 Sep 2020 01:55:03
User entered 'No interference with activity (1)'	System	13 Sep 2020 01:55:03

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:53:12', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4987b96a-8b24-4f4d-9865-055278096c14'	System	13 Sep 2020 01:55:03
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	13 Sep 2020 01:55:03

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:53:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4987b96a-8b24-4f4d-9865-055278096c14'	System	13 Sep 2020 01:55:03
User entered 'Some interference with activity not requiring medical attention (2)'	System	13 Sep 2020 01:55:03

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:54:13', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4987b96a-8b24-4f4d-9865-055278096c14' User entered 'No (N)'	System	13 Sep 2020 01:55:03
	System	13 Sep 2020 01:55:03

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-12T18:55:01', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4987b96a-8b24-4f4d-9865-055278096c14' User entered '12 Sep 2020 18:55'	System	13 Sep 2020 01:55:03
	System	13 Sep 2020 01:55:03

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 3'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:47:14', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8675c092-70ee-4bce-9e87-774000be2bed' User entered 'None (0)'	System	14 Sep 2020 02:48:07
	System	14 Sep 2020 02:48:07

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:47:38', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8675c092-70ee-4bce-9e87-774000be2bed' User entered 'None (0)'	System	14 Sep 2020 02:48:07
	System	14 Sep 2020 02:48:07

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:47:41', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8675c092-70ee-4bce-9e87-774000be2bed' User entered 'None (0)'	System	14 Sep 2020 02:48:07
	System	14 Sep 2020 02:48:07

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:47:44', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8675c092-70ee-4bce-9e87-774000be2bed' User entered 'None (0)'	System	14 Sep 2020 02:48:07
	System	14 Sep 2020 02:48:07

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:47:47', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8675c092-70ee-4bce-9e87-774000be2bed' User entered 'None (0)'	System	14 Sep 2020 02:48:07
	System	14 Sep 2020 02:48:07

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:47:50', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8675c092-70ee-4bce-9e87-774000be2bed' User entered 'None (0)'	System	14 Sep 2020 02:48:07
	System	14 Sep 2020 02:48:07

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:47:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8675c092-70ee-4bce-9e87-774000be2bed' User entered 'No (N)'	System	14 Sep 2020 02:48:07
	System	14 Sep 2020 02:48:07

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-13T19:48:05', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '8675c092-70ee-4bce-9e87-774000be2bed' User entered '13 Sep 2020 19:48'	System	14 Sep 2020 02:48:07
	System	14 Sep 2020 02:48:07

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 4'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:07:04', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e7e1ee9c-99b2-4de7-870f-49c65c9a93a6' User entered 'None (0)'	System	15 Sep 2020 05:07:29
	System	15 Sep 2020 05:07:29

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:07:06', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e7e1ee9c-99b2-4de7-870f-49c65c9a93a6' User entered 'None (0)'	System	15 Sep 2020 05:07:29
	System	15 Sep 2020 05:07:29

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:07:09', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e7e1ee9c-99b2-4de7-870f-49c65c9a93a6' User entered 'None (0)'	System	15 Sep 2020 05:07:29
	System	15 Sep 2020 05:07:29

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:07:12', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e7e1ee9c-99b2-4de7-870f-49c65c9a93a6' User entered 'None (0)'	System	15 Sep 2020 05:07:29
	System	15 Sep 2020 05:07:29

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:07:14', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e7e1ee9c-99b2-4de7-870f-49c65c9a93a6' User entered 'None (0)'	System	15 Sep 2020 05:07:29
	System	15 Sep 2020 05:07:29

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:07:17', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e7e1ee9c-99b2-4de7-870f-49c65c9a93a6' User entered 'None (0)'	System	15 Sep 2020 05:07:29
	System	15 Sep 2020 05:07:29

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:07:20', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e7e1ee9c-99b2-4de7-870f-49c65c9a93a6' User entered 'No (N)'	System	15 Sep 2020 05:07:29
	System	15 Sep 2020 05:07:29

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-14T22:07:26', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'e7e1ee9c-99b2-4de7-870f-49c65c9a93a6' User entered '14 Sep 2020 22:07'	System	15 Sep 2020 05:07:29
	System	15 Sep 2020 05:07:29

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 5'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:27', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff85efd6-9137-45b9-8da3-0f4c25828e6d' User entered 'None (0)'	System	16 Sep 2020 03:17:58
	System	16 Sep 2020 03:17:58

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:29', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff85efd6-9137-45b9-8da3-0f4c25828e6d' User entered 'None (0)'	System	16 Sep 2020 03:17:58
	System	16 Sep 2020 03:17:58

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:34', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff85efd6-9137-45b9-8da3-0f4c25828e6d' User entered 'None (0)'	System	16 Sep 2020 03:17:58
	System	16 Sep 2020 03:17:58

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:38', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff85efd6-9137-45b9-8da3-0f4c25828e6d' User entered 'None (0)'	System	16 Sep 2020 03:17:58
	System	16 Sep 2020 03:17:58

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:41', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff85efd6-9137-45b9-8da3-0f4c25828e6d' User entered 'None (0)'	System	16 Sep 2020 03:17:58
	System	16 Sep 2020 03:17:58

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:45', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff85efd6-9137-45b9-8da3-0f4c25828e6d' User entered 'None (0)'	System	16 Sep 2020 03:17:58
	System	16 Sep 2020 03:17:58

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:49', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff85efd6-9137-45b9-8da3-0f4c25828e6d' User entered 'No (N)'	System	16 Sep 2020 03:17:58
	System	16 Sep 2020 03:17:58

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-15T20:17:54', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ff85efd6-9137-45b9-8da3-0f4c25828e6d' User entered '15 Sep 2020 20:17'	System	16 Sep 2020 03:17:58
	System	16 Sep 2020 03:17:58

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 6'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:18', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b0194cf5-6c87-425e-b766-dd15bf005f5c' User entered 'None (0)'	System	17 Sep 2020 02:36:53
	System	17 Sep 2020 02:36:53

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:21', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b0194cf5-6c87-425e-b766-dd15bf005f5c' User entered 'None (0)'	System	17 Sep 2020 02:36:53
	System	17 Sep 2020 02:36:53

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:31', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b0194cf5-6c87-425e-b766-dd15bf005f5c' User entered 'None (0)'	System	17 Sep 2020 02:36:53
	System	17 Sep 2020 02:36:53

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:34', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b0194cf5-6c87-425e-b766-dd15bf005f5c' User entered 'None (0)'	System	17 Sep 2020 02:36:53
	System	17 Sep 2020 02:36:53

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:38', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b0194cf5-6c87-425e-b766-dd15bf005f5c' User entered 'None (0)'	System	17 Sep 2020 02:36:53
	System	17 Sep 2020 02:36:53

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:40', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b0194cf5-6c87-425e-b766-dd15bf005f5c' User entered 'None (0)'	System	17 Sep 2020 02:36:53
	System	17 Sep 2020 02:36:53

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:45', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b0194cf5-6c87-425e-b766-dd15bf005f5c' User entered 'No (N)'	System	17 Sep 2020 02:36:53
	System	17 Sep 2020 02:36:53

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-16T19:36:49', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b0194cf5-6c87-425e-b766-dd15bf005f5c' User entered '16 Sep 2020 19:36'	System	17 Sep 2020 02:36:53
	System	17 Sep 2020 02:36:53

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	11 Sep 2020 20:31:33
User entered 'Day 7'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:50', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f36f795c-03db-4172-b213-bdb94ffdc2eb' User entered 'None (0)'	System	18 Sep 2020 02:27:24
	System	18 Sep 2020 02:27:24

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:52', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f36f795c-03db-4172-b213-bdb94ffdc2eb' User entered 'None (0)'	System	18 Sep 2020 02:27:24
	System	18 Sep 2020 02:27:24

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:26:57', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f36f795c-03db-4172-b213-bdb94ffdc2eb' User entered 'None (0)'	System	18 Sep 2020 02:27:24
	System	18 Sep 2020 02:27:24

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:27:01', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f36f795c-03db-4172-b213-bdb94ffdc2eb' User entered 'None (0)'	System	18 Sep 2020 02:27:24
	System	18 Sep 2020 02:27:24

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:27:04', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f36f795c-03db-4172-b213-bdb94ffdc2eb' User entered 'None (0)'	System	18 Sep 2020 02:27:24
	System	18 Sep 2020 02:27:24

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:27:11', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f36f795c-03db-4172-b213-bdb94ffdc2eb' User entered 'None (0)'	System	18 Sep 2020 02:27:24
	System	18 Sep 2020 02:27:24

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:27:14', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f36f795c-03db-4172-b213-bdb94ffdc2eb' User entered 'No (N)'	System	18 Sep 2020 02:27:24
	System	18 Sep 2020 02:27:24

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-09-17T19:27:20', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f36f795c-03db-4172-b213-bdb94ffdc2eb' User entered '17 Sep 2020 19:27'	System	18 Sep 2020 02:27:24
	System	18 Sep 2020 02:27:24

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:31:33

US3112262

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:12:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:31:33

US3112262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:53:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:04:44

US3112262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:53:37
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 21:04:44

US3112262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:53:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Sep 2020 21:04:44

US3112262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:53:37
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:04:44

US3112262

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:47:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:54:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:04:51

US3112262

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	18 Sep 2020 21:04:51

US3112262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:57:44
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:21:46

US3112262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:57:44
User entered '25 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:21:46

US3112262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:57:44
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:21:46

US3112262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:57:44
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:21:46

US3112262

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:57:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:21:54

US3112262

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	25 Sep 2020 21:21:54

US3112262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:58:14
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:04:27

US3112262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:58:14
User entered '2 Oct 2020'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:04:27

US3112262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:58:14
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:04:27

US3112262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:58:14
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:04:27

US3112262

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:58:29
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:04:35

US3112262

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	02 Oct 2020 20:04:35

US3112262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:59:41
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:01:40

US3112262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:59:41
User entered '9 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:01:40

US3112262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:59:41
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:01:40

US3112262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'VISIT3'	System	13 Oct 2020 16:01:40

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered '9 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered '11:32'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '9 Oct 2020 11:32'	System	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered '98.2' F	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered empty.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered '66'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'bpm'	System	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered '14'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'breaths/min'	System	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered '132'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:20
User entered '81'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'mmHg'	System	13 Oct 2020 16:07:01

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24

US3112262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24

US3112262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:19

US3112262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:00:53
User entered '9 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:19

US3112262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:01:20
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:38

US3112262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:01:20
User entered '9 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:38

US3112262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:01:20
User entered '11:55'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:38

US3112262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered '9 Oct 2020 11:55'	System	13 Oct 2020 16:07:38

US3112262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:12:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:01:33
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:07:43

US3112262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	13 Oct 2020 16:07:43

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 64'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-10-16T11:11:02', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '995c8ec0-9f78-44d7-be9e-90592a9571b9' User entered 'No (N)'	System	16 Oct 2020 18:11:30
	System	16 Oct 2020 18:11:30

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-10-16T11:11:10', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '995c8ec0-9f78-44d7-be9e-90592a9571b9'	System	16 Oct 2020 18:11:30
User entered 'No (N)'	System	16 Oct 2020 18:11:30

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-10-16T11:11:27', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '995c8ec0-9f78-44d7-be9e-90592a9571b9' User entered '16 Oct 2020 11:11:27'	System	16 Oct 2020 18:11:30
	System	16 Oct 2020 18:11:30

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 71'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-10-21T00:38:08', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a0366d75-9b25-4dfe-b902-86429d1ea33a' User entered 'No (N)'	System	21 Oct 2020 07:38:27
	System	21 Oct 2020 07:38:27

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-10-21T00:38:16', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a0366d75-9b25-4dfe-b902-86429d1ea33a'	System	21 Oct 2020 07:38:27
User entered 'No (N)'	System	21 Oct 2020 07:38:27

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-10-21T00:38:25', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a0366d75-9b25-4dfe-b902-86429d1ea33a' User entered '21 Oct 2020 00:38:25'	System	21 Oct 2020 07:38:27
	System	21 Oct 2020 07:38:27

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 78'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-10-28T12:03:05', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9fc54cfd-9de7-47da-9a5c-2ad47e5d91df' User entered 'No (N)'	System	28 Oct 2020 19:03:17
	System	28 Oct 2020 19:03:17

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-10-28T12:03:09', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9fc54cfd-9de7-47da-9a5c-2ad47e5d91df'	System	28 Oct 2020 19:03:17
User entered 'No (N)'	System	28 Oct 2020 19:03:17

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-10-28T12:03:14', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9fc54cfd-9de7-47da-9a5c-2ad47e5d91df' User entered '28 Oct 2020 12:03:14'	System	28 Oct 2020 19:03:17
	System	28 Oct 2020 19:03:17

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 92'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-11-11T09:32:21', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a6a92130-68f8-4d64-a612-9df15bbbbd83' User entered 'No (N)'	System	11 Nov 2020 17:32:43
	System	11 Nov 2020 17:32:43

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-11-11T09:32:30', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a6a92130-68f8-4d64-a612-9df15bbbbd83'	System	11 Nov 2020 17:32:43
User entered 'No (N)'	System	11 Nov 2020 17:32:43

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-11-11T09:32:39', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a6a92130-68f8-4d64-a612-9df15bbbbd83' User entered '11 Nov 2020 09:32:39'	System	11 Nov 2020 17:32:43
	System	11 Nov 2020 17:32:43

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:16:16
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33
Data entry locked.	System	14 Aug 2020 20:03:33
User entered 'Day 99'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 20:03:33

US3112262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:46:33
Data entry locked.	System	14 Aug 2020 20:03:33
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 20:03:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-11-19T00:09:30', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a9796c45-3abd-4c26-bbb3-51e102503f33'	System	19 Nov 2020 08:09:46
User entered 'No (N)'	System	19 Nov 2020 08:09:46

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-11-19T00:09:38', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a9796c45-3abd-4c26-bbb3-51e102503f33'	System	19 Nov 2020 08:09:46
User entered 'No (N)'	System	19 Nov 2020 08:09:46

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-11-19T00:09:42', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'a9796c45-3abd-4c26-bbb3-51e102503f33' User entered '19 Nov 2020 00:09:42'	System	19 Nov 2020 08:09:46
	System	19 Nov 2020 08:09:46

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-11-22T00:02:07', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ad7e6fb6-45af-4c2b-ac30-6b4454d05806'	System	22 Nov 2020 08:02:32
User entered 'No (N)'	System	22 Nov 2020 08:02:32

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-11-22T00:02:22', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ad7e6fb6-45af-4c2b-ac30-6b4454d05806'	System	22 Nov 2020 08:02:32
User entered 'No (N)'	System	22 Nov 2020 08:02:32

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-11-22T00:02:27', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ad7e6fb6-45af-4c2b-ac30-6b4454d05806' User entered '22 Nov 2020 00:02:27'	System	22 Nov 2020 08:02:32
	System	22 Nov 2020 08:02:32

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-02T00:01:40', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9a37b596-e5c4-403a-9a5b-dafbe508bb8e' User entered 'No (N)'	System	02 Dec 2020 08:01:50
	System	02 Dec 2020 08:01:50

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-02T00:01:44', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9a37b596-e5c4-403a-9a5b-dafbe508bb8e' User entered 'No (N)'	System	02 Dec 2020 08:01:50
	System	02 Dec 2020 08:01:50

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-02T00:01:48', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '9a37b596-e5c4-403a-9a5b-dafbe508bb8e' User entered '02 Dec 2020 00:01:48'	System	02 Dec 2020 08:01:50
	System	02 Dec 2020 08:01:50

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-06T10:31:27', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '654c3186-8459-4099-a65f-9be944728a59' User entered 'No (N)'	System	06 Dec 2020 18:31:37
	System	06 Dec 2020 18:31:37

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-06T10:31:32', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '654c3186-8459-4099-a65f-9be944728a59' User entered 'No (N)'	System	06 Dec 2020 18:31:37
	System	06 Dec 2020 18:31:37

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-06T10:31:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '654c3186-8459-4099-a65f-9be944728a59' User entered '06 Dec 2020 10:31:35'	System	06 Dec 2020 18:31:37
	System	06 Dec 2020 18:31:37

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-13T00:01:40', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '68e6bdd2-d30f-4469-94a7-a7344240f732'	System	13 Dec 2020 08:01:48
User entered 'No (N)'	System	13 Dec 2020 08:01:48

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-13T00:01:42', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '68e6bdd2-d30f-4469-94a7-a7344240f732'	System	13 Dec 2020 08:01:48
User entered 'No (N)'	System	13 Dec 2020 08:01:48

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-13T00:01:45', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '68e6bdd2-d30f-4469-94a7-a7344240f732' User entered '13 Dec 2020 00:01:45'	System	13 Dec 2020 08:01:48
	System	13 Dec 2020 08:01:48

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-20T18:58:03', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '42acf93b-f94a-457e-96b4-5b94c4470be2' User entered 'No (N)'	System	21 Dec 2020 02:58:30
	System	21 Dec 2020 02:58:30

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-20T18:58:06', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '42acf93b-f94a-457e-96b4-5b94c4470be2' User entered 'No (N)'	System	21 Dec 2020 02:58:30
	System	21 Dec 2020 02:58:30

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-20T18:58:27', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '42acf93b-f94a-457e-96b4-5b94c4470be2' User entered '20 Dec 2020 18:58:27'	System	21 Dec 2020 02:58:30
	System	21 Dec 2020 02:58:30

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-28T17:24:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '97475980-1d8c-4dad-9023-d6a5d037d9f4' User entered 'No (N)'	System	29 Dec 2020 01:24:20
	System	29 Dec 2020 01:24:20

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-28T17:24:10', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '97475980-1d8c-4dad-9023-d6a5d037d9f4' User entered 'No (N)'	System	29 Dec 2020 01:24:20

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2020-12-28T17:24:17', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '97475980-1d8c-4dad-9023-d6a5d037d9f4' User entered '28 Dec 2020 17:24:17'	System	29 Dec 2020 01:24:20
	System	29 Dec 2020 01:24:20

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-03T00:02:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fb5ba360-0b6c-4057-8f27-07fde1028c51'	System	03 Jan 2021 08:02:44
User entered 'No (N)'	System	03 Jan 2021 08:02:44

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-03T00:02:39', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fb5ba360-0b6c-4057-8f27-07fde1028c51'	System	03 Jan 2021 08:02:44
User entered 'No (N)'	System	03 Jan 2021 08:02:44

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-03T00:02:42', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fb5ba360-0b6c-4057-8f27-07fde1028c51' User entered '03 Jan 2021 00:02:42'	System	03 Jan 2021 08:02:44
	System	03 Jan 2021 08:02:44

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-10T12:26:28', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'df41f2bc-76ba-4213-968a-6386a14519aa'	System	10 Jan 2021 20:26:40
User entered 'No (N)'	System	10 Jan 2021 20:26:40

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-10T12:26:33', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'df41f2bc-76ba-4213-968a-6386a14519aa'	System	10 Jan 2021 20:26:40
User entered 'No (N)'	System	10 Jan 2021 20:26:40

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-10T12:26:37', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'df41f2bc-76ba-4213-968a-6386a14519aa' User entered '10 Jan 2021 12:26:37'	System	10 Jan 2021 20:26:40
	System	10 Jan 2021 20:26:40

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-17T00:22:26', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7bcdd54-2f71-4296-a2b0-4fb3683846ac' User entered 'No (N)'	System	17 Jan 2021 08:22:58
	System	17 Jan 2021 08:22:58

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-17T00:22:48', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7bcdd54-2f71-4296-a2b0-4fb3683846ac' User entered 'No (N)'	System	17 Jan 2021 08:22:58

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-17T00:22:55', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'b7bcdd54-2f71-4296-a2b0-4fb3683846ac' User entered '17 Jan 2021 00:22:55'	System	17 Jan 2021 08:22:58
	System	17 Jan 2021 08:22:58

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-24T00:08:55', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fb233901-ce9f-4ad6-b881-ddf95190a666'	System	24 Jan 2021 08:09:16
User entered 'No (N)'	System	24 Jan 2021 08:09:16

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-24T00:09:06', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fb233901-ce9f-4ad6-b881-ddf95190a666'	System	24 Jan 2021 08:09:16
User entered 'No (N)'	System	24 Jan 2021 08:09:16

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-24T00:09:12', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fb233901-ce9f-4ad6-b881-ddf95190a666'	System	24 Jan 2021 08:09:16
User entered '24 Jan 2021 00:09:12'	System	24 Jan 2021 08:09:16

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-31T21:14:23', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'efdb50cf-67c0-456d-886a-5caadb7a39f4' User entered 'No (N)'	System	01 Feb 2021 05:14:39

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-31T21:14:26', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'efdb50cf-67c0-456d-886a-5caadb7a39f4'	System	01 Feb 2021 05:14:39
User entered 'No (N)'	System	01 Feb 2021 05:14:39

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-01-31T21:14:32', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'efdb50cf-67c0-456d-886a-5caadb7a39f4' User entered '31 Jan 2021 21:14:32'	System	01 Feb 2021 05:14:39
	System	01 Feb 2021 05:14:39

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-07T00:02:06', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ef3d7d8b-63cc-489a-8cbc-a062faabe5f6'	System	07 Feb 2021 08:02:20
User entered 'No (N)'	System	07 Feb 2021 08:02:20

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-07T00:02:12', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ef3d7d8b-63cc-489a-8cbc-a062faabe5f6'	System	07 Feb 2021 08:02:20
User entered 'No (N)'	System	07 Feb 2021 08:02:20

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-07T00:02:16', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ef3d7d8b-63cc-489a-8cbc-a062faabe5f6'	System	07 Feb 2021 08:02:20
User entered '07 Feb 2021 00:02:16'	System	07 Feb 2021 08:02:20

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-14T02:04:28', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'c97f8a6d-abb5-4958-9987-f5b99053f278' User entered 'No (N)'	System	14 Feb 2021 10:04:43

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-14T02:04:35', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'c97f8a6d-abb5-4958-9987-f5b99053f278' User entered 'No (N)'	System	14 Feb 2021 10:04:43

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-14T02:04:41', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'c97f8a6d-abb5-4958-9987-f5b99053f278' User entered '14 Feb 2021 02:04:41'	System	14 Feb 2021 10:04:43
	System	14 Feb 2021 10:04:43

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-21T22:03:04', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd411396e-a3fc-4a6b-b786-64637cd462f4' User entered 'No (N)'	System	22 Feb 2021 06:03:14
	System	22 Feb 2021 06:03:14

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-21T22:03:07', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd411396e-a3fc-4a6b-b786-64637cd462f4' User entered 'No (N)'	System	22 Feb 2021 06:03:14

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-21T22:03:12', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd411396e-a3fc-4a6b-b786-64637cd462f4' User entered '21 Feb 2021 22:03:12'	System	22 Feb 2021 06:03:14
	System	22 Feb 2021 06:03:14

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-28T09:42:55-08:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0f68cf7f-810f-49ed-b9c7-f4420f6f6c40'	System	28 Feb 2021 17:43:15
User entered 'No (N)'	System	28 Feb 2021 17:43:15

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-28T09:42:58-08:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0f68cf7f-810f-49ed-b9c7-f4420f6f6c40'	System	28 Feb 2021 17:43:15
User entered 'No (N)'	System	28 Feb 2021 17:43:15

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-28T09:43:09-08:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '0f68cf7f-810f-49ed-b9c7-f4420f6f6c40'	System	28 Feb 2021 17:43:15
User entered '28 Feb 2021 17:43:09'	System	28 Feb 2021 17:43:15

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-07T11:23:24-08:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fe1b61f5-d3c1-41d3-b57f-e7a8221e4067'	System	07 Mar 2021 19:23:34
User entered 'No (N)'	System	07 Mar 2021 19:23:34

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-07T11:23:28-08:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fe1b61f5-d3c1-41d3-b57f-e7a8221e4067'	System	07 Mar 2021 19:23:34
User entered 'No (N)'	System	07 Mar 2021 19:23:34

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-07T11:23:32-08:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'fe1b61f5-d3c1-41d3-b57f-e7a8221e4067'	System	07 Mar 2021 19:23:34
User entered '07 Mar 2021 11:23:32'	System	07 Mar 2021 19:23:34

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-14T10:55:53-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd4d30ff7-6f75-4bbe-846c-d88f4fd1a3b'	System	14 Mar 2021 17:56:06
User entered 'No (N)'	System	14 Mar 2021 17:56:06

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-14T10:55:57-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd4d30ff7-6f75-4bbe-846c-d88f4f4d1a3b'	System	14 Mar 2021 17:56:06
User entered 'No (N)'	System	14 Mar 2021 17:56:06

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-14T10:56:03-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'd4d30ff7-6f75-4bbe-846c-d88f4f4d1a3b' User entered '14 Mar 2021 10:56:03'	System	14 Mar 2021 17:56:06
	System	14 Mar 2021 17:56:06

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-21T00:17:55-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'aba9a3b9-97c5-4032-af59-8d8e3d97d4dd'	System	21 Mar 2021 07:18:03
User entered 'No (N)'	System	21 Mar 2021 07:18:03

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-21T00:17:58-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'aba9a3b9-97c5-4032-af59-8d8e3d97d4dd'	System	21 Mar 2021 07:18:03
User entered 'No (N)'	System	21 Mar 2021 07:18:03

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-21T00:18:01-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'aba9a3b9-97c5-4032-af59-8d8e3d97d4dd' User entered '21 Mar 2021 00:18:01'	System	21 Mar 2021 07:18:03
	System	21 Mar 2021 07:18:03

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-29T23:02:23-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2f780b58-ffe0-4e19-9af5-4c85fe8c9118'	System	30 Mar 2021 06:02:48
User entered 'No (N)'	System	30 Mar 2021 06:02:48

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-29T23:02:37-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2f780b58-ffe0-4e19-9af5-4c85fe8c9118'	System	30 Mar 2021 06:02:48
User entered 'No (N)'	System	30 Mar 2021 06:02:48

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-03-29T23:02:44-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '2f780b58-ffe0-4e19-9af5-4c85fe8c9118' User entered '29 Mar 2021 23:02:44'	System	30 Mar 2021 06:02:48
	System	30 Mar 2021 06:02:48

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-04T11:40:23-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '70ccada4-259b-48a3-acd1-d96432b14b78' User entered 'No (N)'	System	04 Apr 2021 18:40:38
	System	04 Apr 2021 18:40:38

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-04T11:40:30-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '70ccada4-259b-48a3-acd1-d96432b14b78'	System	04 Apr 2021 18:40:38
User entered 'No (N)'	System	04 Apr 2021 18:40:38

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-04T11:40:36-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '70ccada4-259b-48a3-acd1-d96432b14b78'	System	04 Apr 2021 18:40:38
User entered '04 Apr 2021 11:40:36'	System	04 Apr 2021 18:40:38

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-11T00:54:47-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '800460c0-2211-424a-87b7-99fc3111d6ac'	System	11 Apr 2021 07:54:59
User entered 'No (N)'	System	11 Apr 2021 07:54:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-11T00:54:53-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '800460c0-2211-424a-87b7-99fc3111d6ac'	System	11 Apr 2021 07:54:59
User entered 'No (N)'	System	11 Apr 2021 07:54:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-11T00:54:57-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '800460c0-2211-424a-87b7-99fc3111d6ac'	System	11 Apr 2021 07:54:59
User entered '11 Apr 2021 00:54:57'	System	11 Apr 2021 07:54:59

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-18T00:39:21-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4dc05913-5b98-46b5-8da8-5cae3c3f281b' User entered 'No (N)'	System	18 Apr 2021 07:39:32
	System	18 Apr 2021 07:39:32

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-18T00:39:27-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4dc05913-5b98-46b5-8da8-5cae3c3f281b' User entered 'No (N)'	System	18 Apr 2021 07:39:32

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-18T00:39:30-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '4dc05913-5b98-46b5-8da8-5cae3c3f281b' User entered '18 Apr 2021 00:39:30'	System	18 Apr 2021 07:39:32
	System	18 Apr 2021 07:39:32

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-25T00:51:23-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f1f81dd1-c5be-4824-9704-69aff6c18df4'	System	25 Apr 2021 07:51:32
User entered 'No (N)'	System	25 Apr 2021 07:51:32

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-25T00:51:26-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f1f81dd1-c5be-4824-9704-69aff6c18df4'	System	25 Apr 2021 07:51:32
User entered 'No (N)'	System	25 Apr 2021 07:51:32

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-04-25T00:51:30-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'f1f81dd1-c5be-4824-9704-69aff6c18df4' User entered '25 Apr 2021 00:51:30'	System	25 Apr 2021 07:51:32
	System	25 Apr 2021 07:51:32

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-05-03T09:11:23-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ce2668ba-e7f6-4ebf-895c-7b19656b4a4f' User entered 'No (N)'	System	03 May 2021 16:17:31
	System	03 May 2021 16:17:31

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-05-03T09:11:27-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ce2668ba-e7f6-4ebf-895c-7b19656b4a4f' User entered 'No (N)'	System	03 May 2021 16:17:31
	System	03 May 2021 16:17:31

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-05-03T09:11:34-07:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: 'ce2668ba-e7f6-4ebf-895c-7b19656b4a4f'	System	03 May 2021 16:17:31
User entered '03 May 2021 09:11:34'	System	03 May 2021 16:17:31

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:46:33

US3112262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:12:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:46:33
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:46:33

US3112262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:12:19

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-28T09:43:17-08:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '44299328-5590-4a9d-a07f-ce67a9a64ba9'	System	28 Feb 2021 17:43:26
User entered 'No (N)'	System	28 Feb 2021 17:43:26

US3112262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:12:19

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:10:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38447CAE-5709-4E4C-9A25-F933AC3CA508)', Time: '2021-02-28T09:43:23-08:00', User OID: 'PatientReportedOutcome (US3112262)', ODM File OID: '44299328-5590-4a9d-a07f-ce67a9a64ba9' User entered '28 Feb 2021 17:43:23'	System	28 Feb 2021 17:43:26
	System	28 Feb 2021 17:43:26

US3112262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:02:58
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Nov 2020 17:33:56

US3112262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:02:58
User entered '06 Nov 2020'	Matthew Musikanth (b) (4)	06 Nov 2020 17:33:56

US3112262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:02:58
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	06 Nov 2020 17:33:56

US3112262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:02:58
User entered empty.	Matthew Musikanth (b) (4)	06 Nov 2020 17:33:56

US3112262

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:53:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:03:04
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Nov 2020 17:33:59

US3112262

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:56:24
User entered 'I'	System	06 Nov 2020 17:33:59

US3112262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:13
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Dec 2020 00:48:30

US3112262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:13
User entered '10 Dec 2020'	Matthew Musikanth (b) (4)	11 Dec 2020 00:48:30

US3112262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:13
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	11 Dec 2020 00:48:30

US3112262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:13
User entered empty.	Matthew Musikanth (b) (4)	11 Dec 2020 00:48:30

US3112262

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 21:03:19
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Dec 2020 00:48:22

US3112262

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered 'I'	System	11 Dec 2020 00:48:22

US3112262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:46:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 20:06:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 16:39:01
Query 'Data is required. Please complete.' answered with 'visit has not occurred yet ' (Site from System).	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:25:36
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 00:25:22
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:25:22
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:24:45

US3112262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:46:23
User entered '12 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 20:06:16
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:25:22
User entered '6 Jan 2021'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:24:45

US3112262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:46:23
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 20:06:16
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:25:22
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:24:45

US3112262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:46:23
User entered empty.	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:24:45

US3112262

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:46:28
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 20:06:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Jan 2021 20:06:26
User entered 'Yes (Y)' reason for change: New Information	Brenda Grande (b) (4) (b) (4)	12 Jan 2021 20:06:26
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 00:25:04
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:25:04
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:24:59
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 00:24:50

US3112262

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered '1'	System	12 Jan 2021 20:06:26
User entered empty.	System	08 Jan 2021 00:24:59
User entered '1'	System	08 Jan 2021 00:24:50

US3112262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:51:57
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:40

US3112262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:51:57
User entered '10 Feb 2021'	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:40

US3112262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:51:57
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:40

US3112262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:51:57
User entered empty.	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:40

US3112262

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:52:03
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:44

US3112262

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered 'I'	System	10 Feb 2021 23:20:44

US3112262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
User closed query 'Visit 4 Day 209 and Visit OL-D57 are both dated 12Mar2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D57 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:02:43
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:48:28
Query 'Visit 4 Day 209 and Visit OL-D57 are both dated 12Mar2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D57 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:52:56
User opened query 'Visit 4 Day 209 and Visit OL-D57 are both dated 12Mar2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D57 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 13:50:02
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:37:02

US3112262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:48:28
User entered '12 Mar 2021'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:37:02

US3112262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:48:28
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:37:02

US3112262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered 'VISIT4'	System	12 Mar 2021 21:37:02

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered '12 Mar 2021'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:59:59
User closed query 'Please clarify. Source indicates time of 10:40. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 19:59:57
Query 'Please clarify. Source indicates time of 10:40. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 21:34:39
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 21:34:29
User entered '10:40' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 21:34:29
User opened query 'Please clarify. Source indicates time of 10:40. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 20:49:40
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered '10:48'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered '12 Mar 2021 10:40'	System	30 Mar 2021 21:34:29
User entered '12 Mar 2021 10:48'	System	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered '98.0' F	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered '61'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered 'bpm'	System	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered '14'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered 'breaths/min'	System	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered '131'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered 'mmHg'	System	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:06
User entered '85'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered 'mmHg'	System	30 Mar 2021 15:32:56

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57

US3112262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57

US3112262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:46
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:37:30

US3112262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:49:46
User entered '12 Mar 2021'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:37:30

US3112262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:50:07
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:37:50

US3112262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:50:07
User entered '12 Mar 2021'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:37:50

US3112262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:50:07
User entered '10:55'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:37:50

US3112262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered '12 Mar 2021 10:55'	System	12 Mar 2021 21:37:50

US3112262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:50:12
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:37:55

US3112262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:51:57
User entered 'I'	System	12 Mar 2021 21:37:55

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:15
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:29

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:15
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:29

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:15
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:29

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 22:39:29

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:08
User closed query 'Data field is actually for date subject signed consent. Please update.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 18:46:05
Query 'Data field is actually for date subject signed consent. Please update.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 23:24:15
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 23:24:02
User entered '6 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 23:24:02
User opened query 'Data field is actually for date subject signed consent. Please update.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 20:18:44
User closed query 'ICF date signed is 24Dec2020. Please update EDC.' (Site from CRA).	(b) (4), (b) (6)	07 Mar 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	07 Mar 2021 18:36:40
Query 'ICF date signed is 24Dec2020. Please update EDC.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	04 Mar 2021 15:53:43
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	04 Mar 2021 15:53:28
User entered '24 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	04 Mar 2021 15:53:28
User opened query 'ICF date signed is 24Dec2020. Please update EDC.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:41:27
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:54
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:08
User entered '0'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 23:24:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:41:45

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:54
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:46:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 23:24:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:41:45

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:54
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:54
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:54
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:22:14
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:54
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:22:14
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:40:54
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '1'	System	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:12:19

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'I'	System	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '170' cm	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '233.4' lb	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '36.70966'	System	06 Jan 2021 22:40:53
DataPoint set to visible.	System	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '170' cm	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '233.4' lb	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '36.70966'	System	06 Jan 2021 22:40:53
DataPoint set to visible.	System	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '10:06'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '6 Jan 2021 10:06'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '98.8' F	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered empty.	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '68'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'bpm'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '16'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'breaths/min'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '133'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '88'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '170' cm	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '233.4' lb	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:12:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '36.70966'	System	06 Jan 2021 22:40:53
DataPoint set to visible.	System	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '11:29'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '6 Jan 2021 11:29'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '98.8' F	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered empty.	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '60'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'bpm'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '16'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'breaths/min'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '148'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:27
User entered '82'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	06 Jan 2021 22:40:53

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:48
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:58

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:48
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:40:58

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:56
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:41:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:41:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:56
User entered empty.	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:41:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mRNA-1273'	System	06 Jan 2021 22:41:19
DataPoint set to visible.	System	06 Jan 2021 22:39:49

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:56
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:41:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:56
User entered '10:58'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:41:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '6 Jan 2021 10:58'	System	06 Jan 2021 22:41:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:56
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:41:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:42:56
User entered 'ONCE'	System	06 Jan 2021 22:41:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 22:41:19

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:43:09
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:41:55

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:43:09
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:41:55

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:43:09
User entered '10:23'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:41:55

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '6 Jan 2021 10:23'	System	06 Jan 2021 22:41:55

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:43:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:42:03

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:12:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:43:18
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:42:03

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
User closed query 'Time in source is 1019. Please update EDC. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 18:09:28 05 Mar 2021 18:09:26
Query 'Time in source is 1019. Please update EDC. ' answered with 'updated' (Site from CRA). DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4) Brenda Grande (b) (4) (b) (4)	04 Mar 2021 15:52:38 04 Mar 2021 15:52:24 04 Mar 2021 15:52:24
User entered '10:19' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	04 Mar 2021 15:52:24
User opened query 'Time in source is 1019. Please update EDC. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 22:43:39 03 Mar 2021 22:43:18
User entered '10:23'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:42:03

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:12:19

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '6 Jan 2021 10:19'	System	04 Mar 2021 15:52:24
User entered '6 Jan 2021 10:23'	System	06 Jan 2021 22:42:03

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:43:44
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	06 Jan 2021 22:42:40

US3112262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '1'	System	06 Jan 2021 22:42:40

US3112262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:47:08
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	13 Jan 2021 23:08:32

US3112262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:47:08
User entered '13 Jan 2021'	Brenda Grande (b) (4) (b) (4)	13 Jan 2021 23:08:32

US3112262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:47:08
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	13 Jan 2021 23:08:32

US3112262

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:47:08
User entered empty.	Brenda Grande (b) (4) (b) (4)	13 Jan 2021 23:08:32

US3112262

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:47:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	13 Jan 2021 23:08:37

US3112262

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'I'	System	13 Jan 2021 23:08:37

US3112262

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '1'	System	13 Jan 2021 23:08:37
DataPoint set to visible.	System	13 Jan 2021 23:08:37

US3112262

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:48:59
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:27:18

US3112262

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:48:59
User entered '3 Feb 2021'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:27:18

US3112262

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:48:59
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:27:18

US3112262

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'OLD29'	System	04 Feb 2021 19:27:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '3 Feb 2021'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '15:06'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '3 Feb 2021 15:06'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Feb 2021 19:28:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Feb 2021 19:28:52
User entered '98.4' F reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:52
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Feb 2021 19:28:18
User entered empty.	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered empty.	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '76'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'bpm'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '16'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'breaths/min'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '128'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '82'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '3 Feb 2021'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '15:52'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '3 Feb 2021 15:52'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Feb 2021 19:28:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Feb 2021 19:28:52
User entered '98.9' F reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:52
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Feb 2021 19:28:18
User entered empty.	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered empty.	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '76'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'bpm'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '16'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'breaths/min'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '128'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:07
User entered '78'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:12:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	04 Feb 2021 19:28:18

US3112262

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:19
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:29:08

US3112262

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:19
User entered '3 Feb 2021'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:29:08

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:42
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:29:36

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:42
User entered empty.	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:29:36

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:42
User entered empty.	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:29:36

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mRNA-1273'	System	04 Feb 2021 19:29:36
DataPoint set to visible.	System	13 Jan 2021 23:08:37

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:42
User entered '3 Feb 2021'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:29:36

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:42
User entered '15:21'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:29:36

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '3 Feb 2021 15:21'	System	04 Feb 2021 19:29:36

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:42
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:29:36

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:42
User entered 'ONCE'	System	04 Feb 2021 19:29:36

US3112262

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:12:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 19:29:36

US3112262

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:50:50
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	04 Feb 2021 19:29:50

US3112262

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'I'	System	04 Feb 2021 19:29:50

US3112262

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:53:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:18

US3112262

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:53:18
User entered '10 Feb 2021'	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:18

US3112262

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:53:18
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:18

US3112262

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:12:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:53:18
User entered empty.	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:18

US3112262

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 22:53:29
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	10 Feb 2021 23:20:22

US3112262

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:12:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'I'	System	10 Feb 2021 23:20:22

US3112262

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:42:47
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:09

US3112262

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:42:47
User entered '12 Mar 2021'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:09

US3112262

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:42:47
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:09

US3112262

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:12:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'OLD57'	System	12 Mar 2021 21:38:09

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User entered '12 Mar 2021'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User entered '10:40'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '12 Mar 2021 10:40'	System	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User entered '98.0' F	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Mar 2021 21:39:12
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	12 Mar 2021 21:39:12
User entered '61' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:39:12
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Mar 2021 21:38:41
User entered '611'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'bpm'	System	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Mar 2021 21:39:12
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	12 Mar 2021 21:39:12
User entered '14' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:39:12
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	12 Mar 2021 21:38:41
User entered '131'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'breaths/min'	System	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User entered '131' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:39:12
User entered '85'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:43:15
User closed query 'Data is required. Please provide.' (Site from System).	System	12 Mar 2021 21:39:12
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	12 Mar 2021 21:39:12
User entered '85' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:39:12
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Mar 2021 21:38:41
User entered empty.	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered 'mmHg'	System	12 Mar 2021 21:39:12
User entered empty.	System	12 Mar 2021 21:38:41

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17

US3112262

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:12:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17

US3112262

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:44:27
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:39:28

US3112262

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:12:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:44:27
User entered '12 Mar 2021'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:39:28

US3112262

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:44:46
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:40:05

US3112262

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:44:46
User entered '12 Mar 2021'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:40:05

US3112262

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:44:46
User entered '10:55'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:40:05

US3112262

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:12:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:10:17
User entered '12 Mar 2021 10:55'	System	12 Mar 2021 21:40:05

US3112262

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:12:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Apr 2021 22:32:56
Signature has been broken.	Matthew Musikanth (b) (4)	07 Apr 2021 22:32:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Apr 2021 22:32:56
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:27:46
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:04:24
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	18 Feb 2021 00:32:51

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered	System	08 Apr 2021 17:00:20
'USA-US062-2021-mRNA-1273-P301000016'		
User entered 'New'	(b) (4), (b) (6)	08 Apr 2021 17:00:20

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Septicemia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 22:40:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 22:40:19
	(b) (4)	
Data point term sent to Coder	System	07 Apr 2021 22:39:51
User entered 'Septicemia'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '26 Mar 2021'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered empty.	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 22:39:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:16:21
User closed query 'Please clarify. Source indicates stop date of 04Apr21. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:16:19
Query 'Please clarify. Source indicates stop date of 04Apr21. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	13 Apr 2021 21:15:10
DataPoint Un-verified.	Matthew Musikanth (b) (4)	13 Apr 2021 21:14:56
Signature has been broken.	Matthew Musikanth (b) (4)	13 Apr 2021 21:14:56
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	13 Apr 2021 21:14:56
User opened query 'Please clarify. Source indicates stop date of 04Apr21. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:38:54
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	07 Apr 2021 22:39:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:16:22
DataPoint Un-verified.	Matthew Musikanth (b) (4)	13 Apr 2021 21:14:56
Signature has been broken.	Matthew Musikanth (b) (4)	13 Apr 2021 21:14:56
User entered '04 Apr 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	13 Apr 2021 21:14:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
User entered empty.	Matthew Musikanth (b) (4)	07 Apr 2021 22:39:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered empty.	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 22:39:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'Yes (Y)'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '0'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '0'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'I'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '28 Mar 2021'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:20:59
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Discharge Summary sent' (Site from Safety).	Matthew Musikanth (b) (4)	26 Apr 2021 16:38:59
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 19:37:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
User entered '31 Mar 2021'	Matthew Musikanth (b) (4)	07 Apr 2021 22:39:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'No (N)'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered empty.	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '0'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '0'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '0'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '0'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered 'I'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '0'	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:16:28
DataPoint Un-verified.	Matthew Musikanth (b) (4)	13 Apr 2021 21:14:56
Signature has been broken.	Matthew Musikanth (b) (4)	13 Apr 2021 21:14:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	13 Apr 2021 21:14:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	07 Apr 2021 22:39:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered empty.	Matthew Musikanth	07 Apr 2021 22:39:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify lab result, E.. coli positive. What was a culture specimen? When was it collected?' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:21:51
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)	27 Apr 2021 13:21:32
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)	27 Apr 2021 13:21:24
Query 'PV Query: Please clarify lab result, E.. coli positive. What was a culture specimen? When was it collected?' answered with 'Blood culture positive with ESBL E. coli isolate. ' (Site from Safety).	Matthew Musikanth (b) (4)	26 Apr 2021 16:43:11
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'None' (Site from Safety).	Matthew Musikanth (b) (4)	26 Apr 2021 16:40:16
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 'Patient COVID screening was negative' (Site from Safety).	Matthew Musikanth (b) (4)	26 Apr 2021 16:39:28
User opened query 'PV Query: Please clarify lab result, E.. coli positive. What was a culture specimen? When was it collected?' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 19:34:11
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 Apr 2021 19:33:42
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 Apr 2021 19:33:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:36:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Abdominal discomfort starting 26Mar2021 led to blood work with abnormal liver function values. Admitted on 28mar2021, positive e.coli culture and admitted for septicemia and prescribed antibiotics. Discharged on 31mar2021 with continuing antibiotics.'	Matthew Musikanth (b) (4)	07 Apr 2021 22:39:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 22:39:50

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 22:39:50

US3112262

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:12:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 22:39:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:12:19

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:51:46
User closed query 'Per ETRTR: According to SAE page "Septicemia", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:20:29
Query 'Per ETRTR: According to SAE page "Septicemia", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' answered with 'conmed updaed' (Site from CRA).	Brenda Grande (b) (4)	09 Apr 2021 21:26:36
User opened query 'Per ETRTR: According to SAE page "Septicemia", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 19:28:12
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:14:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:46:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:49:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:49:25
Data point term sent to Coder	System	21 Aug 2020 18:48:14
User entered 'Vitamin D'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Supplement'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '5000'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'IU (IU)'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'UN UNK 2015'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:48:02

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:50:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:50:29
Data point term sent to Coder	System	21 Aug 2020 18:49:21
User entered 'Fish Oil'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Supplement'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '1000'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'UN UNK 2015'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:49:01

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:25:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:25:55
Data point term sent to Coder Coding entries removed.	System Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:25:11 25 Sep 2020 21:24:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:51:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:51:29
Data point term sent to Coder User entered 'Atorvastatin'	System (b) (4), (b) (6)	21 Aug 2020 18:50:23 21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:15:54
User entered 'HYPERCHOLESTEROLEmia' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:24:41
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 21:24:33
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:05:03
User entered 'Hypercholesterol'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '80'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'UN UNK 2015'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:49:50

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:51:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:51:28
Data point term sent to Coder	System	21 Aug 2020 18:50:24
User entered 'Multivitamin'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Supplement'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '2'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'UN UNK 2015'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 18:50:17

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:56:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 22:56:44
Data point term sent to Coder	System	18 Sep 2020 22:55:01
User entered 'Tylenol'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'muscle aches'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '1000'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '12 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '12 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User entered '1'	System	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User entered '1'	System	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:23
User entered '804 (804)'	System	18 Sep 2020 22:54:56

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 20:08:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 20:08:51
Data point term sent to Coder	System	02 Oct 2020 20:07:46
User entered 'flu vaccine'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'influenza virus prophylaxis'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '0.5'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'mL (mL)'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'once (ONCE)'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'Intramuscular (INTRAMUSCULAR)'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '30 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:18
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	02 Oct 2020 20:07:18
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	02 Oct 2020 20:07:10
User entered '30 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:17:51
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User entered empty.	System	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User entered empty.	System	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:19
User entered empty.	System	02 Oct 2020 20:07:10

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 21:42:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 21:42:48
Data point term sent to Coder	System	12 Mar 2021 21:42:14
User entered 'shingrix'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered 'shingles Prophylaxis'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered '.5'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered 'mL (mL)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered empty.	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered 'once (ONCE)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered empty.	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered 'Intramuscular (INTRAMUSCULAR)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered empty.	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered '26 Feb 2021'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered '0'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered '26 Feb 2021'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 20:17:52
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User entered empty.	System	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User entered empty.	System	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:15
User entered empty.	System	12 Mar 2021 21:42:04

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: ERTAPENEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:15:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:15:04
Data point term sent to Coder	System	09 Apr 2021 21:28:43
User entered 'ertapenem'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'septicemia'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'unknown'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'Other (OTHER)'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'unknown'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'other (OTHER)'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'unknown'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'Intravenous (INTRAVENOUS)'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered '28 Mar 2021'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered '04 Apr 2021'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:42
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:12:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 21:27:51

US3112262

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:12:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:21:05
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 22:04:51
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	18 Feb 2021 00:32:46

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered	System	08 Apr 2021 17:00:20
'USA-US062-2021-MRNA-1273-P301000016'		

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Yes (Y)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Yes (Y)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Todd'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Simmons'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered '9040 Friars Road Suite 540'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'San Diego'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'CA'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered '92108'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'US'	System	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Apr 2021 13:22:38
User entered '2'	System	14 Apr 2021 12:44:22
User entered '1'	System	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered	System	08 Apr 2021 17:00:20
'USA-US062-2021-MRNA-1273-P301000016'		

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Yes (Y)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Yes (Y)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Todd'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Simmons'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered '9040 Friars Road Suite 540'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'San Diego'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'CA'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered '92108'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'US'	System	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Apr 2021 13:22:38
User entered '2'	System	14 Apr 2021 12:44:22
User entered '1'	System	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:12:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
User entered '08/Apr/2021 13:00'	System	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:12:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered	System	08 Apr 2021 17:00:20
'USA-US062-2021-MRNA-1273-P301000016'		

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Yes (Y)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Yes (Y)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Todd'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Simmons'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered '9040 Friars Road Suite 540'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'San Diego'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'CA'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered '92108'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'US'	System	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Apr 2021 13:22:38
User entered '2'	System	14 Apr 2021 12:44:22
User entered '1'	System	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:12:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:48:39
User entered '14/Apr/2021 08:44'	System	14 Apr 2021 12:44:22

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:12:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:37:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:48:39
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 12:44:22

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered	System	08 Apr 2021 17:00:20
'USA-US062-2021-MRNA-1273-P301000016'		

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Yes (Y)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Yes (Y)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'No (N)'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Todd'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'Simmons'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered '9040 Friars Road Suite 540'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:10:01
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'San Diego'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'CA'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered '92108'	System	08 Apr 2021 17:00:20

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:29:16
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:10:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 17:00:44
User entered 'US'	System	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:12:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Apr 2021 13:22:38
User entered '2'	System	14 Apr 2021 12:44:22
User entered '1'	System	08 Apr 2021 17:00:39

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:12:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:42
	(b) (4)	
User entered '27/Apr/2021 06:22'	System	27 Apr 2021 13:22:38

US3112262

Folder: SAE USA-US062-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:12:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:42
User entered 'I'	(b) (4), (b) (6)	27 Apr 2021 13:22:38