

US3262259 (Prod: AB Clinical Trials - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:19:44

All time stamps listed in this document are displayed in GMT

US3262259

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 17:10:38

Generated On: 09 Jun 2021 16:19:44

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[Participant ID](#)

US3262259

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

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US3262259

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
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) 13 Feb 2021 00:18:28

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	01 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

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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) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Condition	PINCHED NERVE
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Condition	OVERWEIGHT
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 10:05
Height (xxx.x)	179 cm
Weight (xxx.x)	259.6 lb
BMI (xxx.x)	36.82781 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 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) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

CASINO WORKER

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:18:29

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 17:29:42

Generated On: 09 Jun 2021 16:19:44

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 146069

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) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Height	179.0 cm
Weight	259.6 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Height	179.0 cm
Weight	259.6 lb
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)	09 SEP 2020
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 08:05
Temperature (xxx.x)	97.9 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Height	179.0 cm
Weight	259.6 lb
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)	09 SEP 2020
Time of assessment (00:00-23:59)	09:19 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 09:19
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

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) 09 SEP 2020

What was the treatment time? (00:00-23:59) 08:49 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 08:49

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) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 SEP 2020
Collection time (00:00-23:59)	08:17 (24 HR)
Collection date and time (derived)	09 SEP 2020 08:17

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:10	09 SEP 2020 08:10
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 09:31

PC Open Date & Time

09 SEP 2020 09:09

PC Close Date & Time

09 SEP 2020 11:39

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**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 94.7 °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	10 SEP 2020 00:16
PC Open Date & Time	09 SEP 2020 12:34
PC Close Date & Time	10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**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

96.5 °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

10 SEP 2020 15:28

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**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

95.6 °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

12 SEP 2020 00:24

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**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

97.4 °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

12 SEP 2020 19:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**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

97.9 °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

13 SEP 2020 13:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**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

97.3 °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

14 SEP 2020 12:44

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 15:59

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**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

09 SEP 2020 09:32

PC Open Date & Time

09 SEP 2020 09:09

PC Close Date & Time

09 SEP 2020 11:39

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**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

10 SEP 2020 00:17

PC Open Date & Time

09 SEP 2020 12:34

PC Close Date & Time

10 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**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

10 SEP 2020 15:29

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**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

12 SEP 2020 00:24

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**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

12 SEP 2020 19:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**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

13 SEP 2020 13:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**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

14 SEP 2020 12:45

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**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

15 SEP 2020 15:59

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**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 ☐

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 09:32
PC Open Date & Time	09 SEP 2020 09:09
PC Close Date & Time	09 SEP 2020 11:39

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**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 ☐

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 00:17
PC Open Date & Time	09 SEP 2020 12:34
PC Close Date & Time	10 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**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

45 of 1867

EAB) (1725)

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 15:29
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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 ☒

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EAB) (1725)



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 00:25
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**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

49 of 1867

EAB) (1725)

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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

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EAB) (1725)

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:32
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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 ☒

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:45
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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 ☒



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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

US3262259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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	VISIT2



US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

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)	07 OCT 2020
Time of assessment (00:00-23:59)	09:38 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 09:38
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

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)	07 OCT 2020
Time of assessment (00:00-23:59)	11:43 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 11:43
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3262259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

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) 07 OCT 2020

What was the treatment time? (00:00-23:59) 10:43 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 10:43

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

US3262259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 OCT 2020
Collection time (00:00-23:59)	09:51 (24 HR)
Collection date and time (derived)	07 OCT 2020 09:51

US3262259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:40	07 OCT 2020 09:40
Nasopharyngeal Swab 2	No		

US3262259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 11:48

PC Open Date & Time

07 OCT 2020 11:03

PC Close Date & Time

07 OCT 2020 13:33



US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**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 96.5 °F

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

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

PC Time Stamp	08 OCT 2020 00:07
PC Open Date & Time	07 OCT 2020 14:28
PC Close Date & Time	08 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 17:25

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**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

97.0 °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

09 OCT 2020 20:28

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 05:10

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**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

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 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 07:44

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp 13 OCT 2020 15:31

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**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

07 OCT 2020 11:48

PC Open Date & Time

07 OCT 2020 11:03

PC Close Date & Time

07 OCT 2020 13:33



US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**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

08 OCT 2020 00:07

PC Open Date & Time

07 OCT 2020 14:28

PC Close Date & Time

08 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**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

08 OCT 2020 17:25

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**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

09 OCT 2020 20:29

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**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

11 OCT 2020 05:10

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**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

13 OCT 2020 07:44

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**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

13 OCT 2020 15:31

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**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 ☐



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 11:49
PC Open Date & Time	07 OCT 2020 11:03
PC Close Date & Time	07 OCT 2020 13:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**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 ☐

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 00:08
PC Open Date & Time	07 OCT 2020 14:28
PC Close Date & Time	08 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**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 ☒

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 17:26
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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 ☒

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 20:29
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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 ☒

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EAB) (1725)



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 05:10
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**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 ☐

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

Yes ☐

PC Time stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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

99 of 1867

EAB) (1725)

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 07:44
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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 ☒

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 15:32
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3262259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262259

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:18:28

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 NOV 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

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 NOV 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 09:05
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3262259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

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.*



US3262259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 NOV 2020
Collection time (00:00-23:59)	09:10 (24 HR)
Collection date and time (derived)	10 NOV 2020 09:10

US3262259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:18:29

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

10 NOV 2020 21:27:22

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3262259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

16 NOV 2020 04:31:31

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 NOV 2020 15:11:02
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 NOV 2020 03:06:53
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 DEC 2020 17:59:42
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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	14 DEC 2020 19:05:46
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59



US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

20 DEC 2020 12:00:45

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

25 DEC 2020 00:25:18

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

03 JAN 2021 12:00:33

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

15 JAN 2021 04:12:32

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

22 JAN 2021 00:16:24

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

29 JAN 2021 04:15:17

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59



US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 11:59:40

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

14 FEB 2021 13:08:38

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

22 FEB 2021 17:59:31

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

28 FEB 2021 23:48:27

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 17:02:27

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 07:31:03

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 22:57:21

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

26 MAR 2021 12:12:24

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59



US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

02 APR 2021 06:30:29

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

10 APR 2021 23:13:41

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

16 APR 2021 00:16:42

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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

27 APR 2021 12:00:32

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 MAY 2021 12:09:48
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59
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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 AUG 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 SEP 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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°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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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="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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JAN 2022 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT

DAY 558

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 APR 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 APR 2022 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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22 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUN 2022 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59
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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2022 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2022 23:59

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**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 ☐

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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21 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 OCT 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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 <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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2022 23:59

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US3262259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

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"/>

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2022 23:59

US3262259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:19:44

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 23:48:13

US3262259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:57:57

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:57:57

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 10:00
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3262259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

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.*

US3262259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	10:08 (24 HR)
Collection date and time (derived)	30 MAR 2021 10:08

US3262259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

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

**US3262259**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3262259

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:19:44

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"/>

**US3262259**

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

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

**Generated On: 09 Jun 2021 16:19:44**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3262259

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

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

Visit date (dd MMM yyyy)	26 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3262259

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Date of updated informed consent ( <i>dd MMM yyyy</i> )	26 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> )	26 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

US3262259

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3262259

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	26 JAN 2021
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 10:32
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3262259

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	26 JAN 2021
Time of assessment (00:00-23:59)	11:11 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 11:11
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3262259

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

26 JAN 2021

---

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

---

US3262259

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

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) 26 JAN 2021

What was the treatment time? (00:00-23:59) 10:39 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 10:39

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

US3262259

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00-23:59)	10:37 (24 HR)
Collection date and time (derived)	26 JAN 2021 10:37

US3262259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	10:34
Collection Date and Time (derived)	26 JAN 2021 10:34



US3262259

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3262259

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 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

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

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 ( <i>dd MMM yyyy</i> )	3 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	09:09 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 09:09
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> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	86 mmHg
Diastolic Blood Pressure units	MMHG

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

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)	3 MAR 2021
Time of assessment (00:00-23:59)	09:53 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 09:53
Temperature (xxx.x)	98.5 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)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3262259

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:10:38

Generated On: 09 Jun 2021 16:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 MAR 2021

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

US3262259

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 17:10:38

Generated On: 09 Jun 2021 16:19:44

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 MAR 2021

What was the treatment time? (00:00-23:59) 09:18 (24 HR)

Treatment Date and Time (derived) 3 MAR 2021 09:18

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



US3262259

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:10:38

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3262259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3262259

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3262259

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	30 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:00 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 10:00
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> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3262259

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

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.*

US3262259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:10:39

Generated On: 09 Jun 2021 16:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	10:08 (24 HR)
Collection date and time (derived)	30 MAR 2021 10:08

US3262259

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 May 2021 19:55:10

Generated On: 09 Jun 2021 16:19:44

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 19:55:09

Generated On: 09 Jun 2021 16:19:44

AEID	USA-US069-2021-MRNA-1273-P30 1000007
Adverse event	DIARRHEA OF UNKNOWN ETIOLOGY
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)	01 MAY 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	01 MAY 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 19:55:09

Generated On: 09 Jun 2021 16:19:44

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

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 20:37:26

Generated On: 09 Jun 2021 16:19:44

---

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

Yes ☒

No ☐

---

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

---

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 19:17:10

Generated On: 09 Jun 2021 16:19:44

Name of Medication AMODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 19:17:10

Generated On: 09 Jun 2021 16:19:44

	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 2012	
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) 19 Apr 2021 19:17:10

Generated On: 09 Jun 2021 16:19:44

Name of Medication BENAZEPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Apr 2021 19:17:10

Generated On: 09 Jun 2021 16:19:44

	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 2016	
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 (3)

Data signed: (b) (4) 19 Apr 2021 19:17:10

Generated On: 09 Jun 2021 16:19:44

Name of Medication HYDROCHLOROTHAIZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Apr 2021 19:17:10

Generated On: 09 Jun 2021 16:19:44

	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 2016	
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) 19 Apr 2021 19:17:10

Generated On: 09 Jun 2021 16:19:44

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication PINCHED NERVE

Dose per administration 600

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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US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 19:17:10

Generated On: 09 Jun 2021 16:19:44

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3262259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 20:18:46

Generated On: 09 Jun 2021 16:19:44

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3262259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:19:44

---

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

---

US3262259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:19:44

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 ☐

US3262259

Folder: SAE USA-US069-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 19:55:10

Generated On: 09 Jun 2021 16:19:44

SAEID	USA-US069-2021-MRNA-1273-P301000007
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3262259

Folder: SAE USA-US069-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 19:55:10

Generated On: 09 Jun 2021 16:19:44

SAEID	USA-US069-2021-MRNA-1273-P301000007
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	03/MAY/2021 14:20
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

US3262259 (Prod: AB Clinical Trials - Hunt - PPDS)

**US3262259**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:19:44**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'US3262259'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 17:45:04

US3262259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:45:26

US3262259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '01 SEP 2020'	RWS_ENDPOINT	01 Sep 2020 17:45:12
	ENDPOINT (b) (4)	

US3262259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:19:44

[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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 17:45:26

**US3262259**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'SCRN'	System	01 Sep 2020 17:45:26

US3262259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:19:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered (b) (6) 1966'	RWS_ENDPOINT	01 Sep 2020 17:45:14
	ENDPOINT (b) (4)	

US3262259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:19:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '54'	(b) (4), (b) (6)	01 Sep 2020 17:45:47



**US3262259**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:19:44**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'YEARS'	System	01 Sep 2020 17:45:47

**US3262259**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:19:44**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered '54'	System	01 Sep 2020 17:46:26

US3262259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:19:44

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Male (M)'	(b) (4), (b) (6)	01 Sep 2020 17:45:47

US3262259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:19:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Sep 2020 17:45:47

**US3262259**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:19:44**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 17:45:47

US3262259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:19:44

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:45:47

**US3262259**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:19:44**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:45:47

US3262259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:19:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:45:47



US3262259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:19:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:45:47

**US3262259**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:19:44**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:45:47

US3262259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:19:44

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:45:47

US3262259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:19:44

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:45:47

**US3262259**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:19:44**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:45:47

US3262259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:19:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '01 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 17:46:26

**US3262259**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'Sep 2020'	System	01 Sep 2020 17:46:26

**US3262259**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered '2020'	System	01 Sep 2020 17:46:26



US3262259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:19:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	01 Sep 2020 17:46:26

US3262259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User closed query 'Enrollment is recorded as No; however, met all criteria is recorded as Yes. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:26:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	09 Sep 2020 16:26:34
	(b) (4)	
User opened query 'Enrollment is recorded as No; however, met all criteria is recorded as Yes. Please review and reconcile.' (Site from System).	System	09 Sep 2020 15:57:31
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:46:26

US3262259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:19:44

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User closed query 'Was participant enrolled in the study is Yes, however reason for screen fail has been provided. Please correct.' (Site from System).	System	26 Jan 2021 18:47:05
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4)	26 Jan 2021 18:47:05
	(b) (4)	
User opened query 'Was participant enrolled in the study is Yes, however reason for screen fail has been provided. Please correct.' (Site from System).	System	09 Sep 2020 16:26:34
User entered 'Inclusion/Exclusion (INCLUSION/EXCLUSION)'	(b) (4), (b) (6)	01 Sep 2020 17:46:26

US3262259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:19:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:46:26

US3262259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:19:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:46:26

US3262259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:19:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered empty.	RWS_ENDPOINT	01 Sep 2020 17:45:12
	ENDPOINT (b) (4)	

US3262259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:19:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered '1'	System	09 Sep 2020 16:26:34
User entered empty.	System	01 Sep 2020 17:46:36

US3262259

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User closed query 'Did the subject meet all eligibility criteria? is marked "No", but Subject was randomized Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 15:57:31
Query 'Did the subject meet all eligibility criteria? is marked "No", but Subject was randomized Please review and provide any needed correction.' answered by data change (Site from System).	System	09 Sep 2020 15:57:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:57:31
User opened query 'Did the subject meet all eligibility criteria? is marked "No", but Subject was randomized Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 15:45:32
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:46:36



US3262259

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:19:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:40:37

US3262259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:19:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:34:28
Query 'Per DM CLR: Please note that there is no Con Alia Bober Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Con med listed.' (Site from DM).	(b) (4)	22 Oct 2020 15:22:54
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 00:15:23
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:42:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:42:49
Data point term sent to Coder	System	14 Sep 2020 18:42:00
User entered 'Hypertension'	(b) (4), (b) (6)	14 Sep 2020 18:41:19

**US3262259**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'un UNK 2012'	(b) (4), (b) (6)	14 Sep 2020 18:41:19

**US3262259**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:41:19

**US3262259**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:41:19

US3262259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:41:19

**US3262259**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:41:19

**US3262259**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'Jan 2012'	System	14 Sep 2020 18:41:19



**US3262259**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered '2012'	System	14 Sep 2020 18:41:19

US3262259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered empty.	System	14 Sep 2020 18:41:19

**US3262259**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered empty.	System	14 Sep 2020 18:41:19

US3262259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:19:44

Condition

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 21:51:13
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Nerve compression, LLT: Pinched nerve - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 23:40:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 23:40:01
Data point term sent to Coder	System	08 Apr 2021 23:39:27
Coding entries removed.	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 23:39:02
Signature has been broken.	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 23:39:02
User entered 'PINCHED NERVE' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 23:39:02
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	13 Feb 2021 00:18:29
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e., sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:37:35
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e., sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:18:08
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 06:29:43
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 06:29:43
Data point term sent to Coder	System	14 Sep 2020 18:43:03
User entered 'Left lower extremity neuropathy'	(b) (4), (b) (6)	14 Sep 2020 18:42:04

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EAB) (1725)

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**US3262259**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'un UNK 2019'	(b) (4), (b) (6)	14 Sep 2020 18:42:04

**US3262259**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:42:04

**US3262259**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:42:04

US3262259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:42:04



**US3262259**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:42:04

**US3262259**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'Jan 2019'	System	14 Sep 2020 18:42:04

**US3262259**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered '2019'	System	14 Sep 2020 18:42:04

**US3262259**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered empty.	System	14 Sep 2020 18:42:04

US3262259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered empty.	System	14 Sep 2020 18:42:04

US3262259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:19:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 13:35:33
Query 'Per DM CLR: Please note that there is no Con Alia Bober Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'No con med listed.' (Site from DM).	(b) (4)	22 Oct 2020 15:23:17
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 00:15:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 18:43:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 18:43:49
Data point term sent to Coder	System	14 Sep 2020 18:43:05
User entered 'Asthma'	(b) (4), (b) (6)	14 Sep 2020 18:42:24

**US3262259**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'un UNK 2000'	(b) (4), (b) (6)	14 Sep 2020 18:42:24

**US3262259**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:42:24



**US3262259**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:42:24

**US3262259**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:42:24

US3262259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:19:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:42:24

**US3262259**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'Jan 2000'	System	14 Sep 2020 18:42:24

**US3262259**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered '2000'	System	14 Sep 2020 18:42:24

US3262259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered empty.	System	14 Sep 2020 18:42:24

US3262259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered empty.	System	14 Sep 2020 18:42:24

US3262259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:19:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Overweight, LLT: Overweight - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:44:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 18:44:49
	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 18:44:11
User entered 'Overweight'	(b) (4), (b) (6)	14 Sep 2020 18:44:00



US3262259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'un UNK 2005'	(b) (4), (b) (6)	14 Sep 2020 18:44:00

**US3262259**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:44:00

**US3262259**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:44:00

**US3262259**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:44:00

**US3262259**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:44:00

**US3262259**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'Jan 2005'	System	14 Sep 2020 18:44:00

**US3262259**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered '2005'	System	14 Sep 2020 18:44:00

US3262259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered empty.	System	14 Sep 2020 18:44:00



US3262259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered empty.	System	14 Sep 2020 18:44:00

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '01 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '10:05'	(b) (4), (b) (6)	14 Sep 2020 18:45:29

**US3262259**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered '01 Sep 2020 10:05'	System	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '179' cm	(b) (4), (b) (6)	14 Sep 2020 18:45:29
DataPoint set to visible.	System	09 Sep 2020 16:26:34

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '259.6' lb	(b) (4), (b) (6)	14 Sep 2020 18:45:29
DataPoint set to visible.	System	09 Sep 2020 16:26:34

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered '36.82781'	System	14 Sep 2020 18:45:29
DataPoint set to visible.	System	09 Sep 2020 16:26:34



**US3262259**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'kg/m2'	System	14 Sep 2020 18:45:29
DataPoint set to visible.	System	09 Sep 2020 16:26:34

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '97.6' F	(b) (4), (b) (6)	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:45:29

**US3262259**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '58'	(b) (4), (b) (6)	14 Sep 2020 18:45:29

**US3262259**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'bpm'	System	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '12'	(b) (4), (b) (6)	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'breaths/min'	System	14 Sep 2020 18:45:29



US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '119'	(b) (4), (b) (6)	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'mmHg'	System	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '75'	(b) (4), (b) (6)	14 Sep 2020 18:45:29

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User entered 'mmHg'	System	14 Sep 2020 18:45:29

**US3262259**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13

US3262259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13

US3262259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:46:36

US3262259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 19:07:15
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 18:46:36
User entered '01 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:46:36



US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

[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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

[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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32



US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

[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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'Casino Worker'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:48:32



US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

[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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

**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 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:19:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:51:13
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:48:32

US3262259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	09 Sep 2020 16:26:00

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	09 Sep 2020 16:26:00

US3262259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	09 Sep 2020 16:26:00



**US3262259**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'VISIT1'	System	09 Sep 2020 16:26:00

US3262259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	19 Feb 2021 17:29:42
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 15:45:32

US3262259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:19:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	19 Feb 2021 17:29:42
User entered '146069'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	09 Sep 2020 15:45:32

US3262259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	19 Feb 2021 17:29:42
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 15:45:32

US3262259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	19 Feb 2021 17:29:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:50:04

US3262259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	19 Feb 2021 17:29:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:50:04

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	19 Feb 2021 17:29:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:50:04

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:19:44**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	19 Feb 2021 17:29:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:50:04



**US3262259**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:19:44**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	19 Feb 2021 17:29:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:50:04

US3262259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:19:44

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	19 Feb 2021 17:29:42
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	17 Feb 2021 23:13:40
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 17:19:06
User entered 'No (N)'		17 Feb 2021 17:19:02
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).		11 Nov 2020 18:43:52
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:51:14
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:59:04

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '179.0' cm	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '259.6' lb	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '179.0' cm	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '259.6' lb	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User accepted default value 'Pre-Dose (PREDOSE)'		14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24



US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '08:05'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '09 Sep 2020 08:05'	System	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '64'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'bpm'	System	14 Sep 2020 19:28:24



US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '14'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'breaths/min'	System	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '121'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '71'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '179.0' cm	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '259.6' lb	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24



US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User accepted default value 'Post-Dose (POSTDOSE)'		14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09:19'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '09 Sep 2020 09:19'	System	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24



US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '62'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'bpm'	System	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '12'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'breaths/min'	System	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '120'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '76'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:24

US3262259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	14 Sep 2020 19:28:24



**US3262259**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:19:44**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:43

US3262259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:28:43

US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	09 Sep 2020 16:27:40

US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) Daisy Langarica (b) (4)	09 Sep 2020 16:27:40

US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) Daisy Langarica (b) (4)	09 Sep 2020 16:27:40
	(b) (4)	

US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 16:27:40

US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	09 Sep 2020 16:27:40
	(b) (4)	

US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '08:49'	(b) (4) Daisy Langarica (b) (4)	09 Sep 2020 16:27:40



US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '09 Sep 2020 08:49'	System	09 Sep 2020 16:27:40

US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langarica (b) (4)	09 Sep 2020 16:27:40

US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'ONCE'	System	09 Sep 2020 16:27:40

US3262259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 16:27:40

US3262259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:29:16

US3262259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:29:16

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '08:17'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:29:16

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '09 Sep 2020 08:17'	System	14 Sep 2020 19:29:16



US3262259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:29:36

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		14 Sep 2020 19:29:36

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:29:36

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '08:10'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:29:36

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '09 Sep 2020 08:10'	System	14 Sep 2020 19:29:36

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		14 Sep 2020 19:29:36

US3262259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:29:36

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:19:44**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:29:36



**US3262259**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered empty.	System	14 Sep 2020 19:29:36

US3262259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	09 Sep 2020 16:27:51

**US3262259**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	09 Sep 2020 16:27:51

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:31:26', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aa8bfa4a-6400-48cb-a6cf-fc27813658c4' User entered 'Yes (Y)'	System	09 Sep 2020 16:31:48
	System	09 Sep 2020 16:31:48

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:31:33', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aa8bfa4a-6400-48cb-a6cf-fc27813658c4' User entered '98.1'	System	09 Sep 2020 16:31:48
	System	09 Sep 2020 16:31:48

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:31:39', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aa8bfa4a-6400-48cb-a6cf-fc27813658c4'	System	09 Sep 2020 16:31:48
User entered 'No (N)'	System	09 Sep 2020 16:31:48

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:31:45', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aa8bfa4a-6400-48cb-a6cf-fc27813658c4' User entered '09 Sep 2020 09:31'	System	09 Sep 2020 16:31:48
	System	09 Sep 2020 16:31:48



US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Sep 2020 09:09'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Sep 2020 11:39'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:16:32', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '9368a6e9-37a2-4527-9922-caad93bef0fa' User entered 'Yes (Y)'	System	10 Sep 2020 07:16:52
	System	10 Sep 2020 07:16:52

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:16:37', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '9368a6e9-37a2-4527-9922-caad93bef0fa' User entered '94.7'	System	10 Sep 2020 07:16:52
	System	10 Sep 2020 07:16:52

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:16:41', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '9368a6e9-37a2-4527-9922-caad93bef0fa' User entered 'No (N)'	System	10 Sep 2020 07:16:52
	System	10 Sep 2020 07:16:52

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:16:45', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '9368a6e9-37a2-4527-9922-caad93bef0fa' User entered '10 Sep 2020 00:16'	System	10 Sep 2020 07:16:52
	System	10 Sep 2020 07:16:52

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Sep 2020 12:34'	System	09 Sep 2020 16:27:40



US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 2'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:26:32', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8bbbfed-da23-4bcb-9efb-fc86baf62477'	System	10 Sep 2020 22:28:51
User entered 'Yes (Y)'	System	10 Sep 2020 22:28:51

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:28:39', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8bbbfed-da23-4bcb-9efb-fc86baf62477'	System	10 Sep 2020 22:28:51
User entered '96.5'	System	10 Sep 2020 22:28:51

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:28:42', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8bbbfed-da23-4bcb-9efb-fc86baf62477'	System	10 Sep 2020 22:28:51
User entered 'No (N)'	System	10 Sep 2020 22:28:51

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:28:47', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8bbbfed-da23-4bcb-9efb-fc86baf62477'	System	10 Sep 2020 22:28:51
User entered '10 Sep 2020 15:28'	System	10 Sep 2020 22:28:51

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:27:40



US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 3'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:05', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2bf94a9b-3d46-4d58-a73a-7de2ffa7567f' User entered 'Yes (Y)'	System	12 Sep 2020 07:24:20
	System	12 Sep 2020 07:24:20

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:11', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2bf94a9b-3d46-4d58-a73a-7de2ffa7567f' User entered '95.6'	System	12 Sep 2020 07:24:20
	System	12 Sep 2020 07:24:20

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:15', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2bf94a9b-3d46-4d58-a73a-7de2ffa7567f' User entered 'No (N)'	System	12 Sep 2020 07:24:20
	System	12 Sep 2020 07:24:20

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:18', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2bf94a9b-3d46-4d58-a73a-7de2ffa7567f' User entered '12 Sep 2020 00:24'	System	12 Sep 2020 07:24:20
	System	12 Sep 2020 07:24:20

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 4'	System	09 Sep 2020 16:27:40



US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:24', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '27e025d9-e020-4c39-b662-df9fbeeceeded4' User entered 'Yes (Y)'	System	13 Sep 2020 02:01:39
	System	13 Sep 2020 02:01:39

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:28', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '27e025d9-e020-4c39-b662-df9fbeeceeded4' User entered '97.4'	System	13 Sep 2020 02:01:39
	System	13 Sep 2020 02:01:39

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:32', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '27e025d9-e020-4c39-b662-df9fbeeceeded4' User entered 'No (N)'	System	13 Sep 2020 02:01:39
	System	13 Sep 2020 02:01:39

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:36', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '27e025d9-e020-4c39-b662-df9fbeeceeded4' User entered '12 Sep 2020 19:01'	System	13 Sep 2020 02:01:39
	System	13 Sep 2020 02:01:39

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 5'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:30:44', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '19f7961d-1c14-4ae6-9f68-002aa28d3945'	System	13 Sep 2020 20:31:20
User entered 'Yes (Y)'	System	13 Sep 2020 20:31:20



US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:30:52', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '19f7961d-1c14-4ae6-9f68-002aa28d3945' User entered '97.9'	System	13 Sep 2020 20:31:20
	System	13 Sep 2020 20:31:20

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:30:59', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '19f7961d-1c14-4ae6-9f68-002aa28d3945'	System	13 Sep 2020 20:31:20
User entered 'No (N)'	System	13 Sep 2020 20:31:20

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:31:18', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '19f7961d-1c14-4ae6-9f68-002aa28d3945'	System	13 Sep 2020 20:31:20
User entered '13 Sep 2020 13:31'	System	13 Sep 2020 20:31:20

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 6'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:44:35', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '204f09c1-1765-43c2-b78d-a8ae362e0433'	System	14 Sep 2020 19:44:50
User entered 'Yes (Y)'	System	14 Sep 2020 19:44:50

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:44:41', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '204f09c1-1765-43c2-b78d-a8ae362e0433' User entered '97.3'	System	14 Sep 2020 19:44:50
	System	14 Sep 2020 19:44:50



US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:44:44', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '204f09c1-1765-43c2-b78d-a8ae362e0433'	System	14 Sep 2020 19:44:50
User entered 'No (N)'	System	14 Sep 2020 19:44:50

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:44:48', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '204f09c1-1765-43c2-b78d-a8ae362e0433'	System	14 Sep 2020 19:44:50
User entered '14 Sep 2020 12:44'	System	14 Sep 2020 19:44:50

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 7'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:58:51', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aff33a79-e7ba-408e-bcf9-50cb64ab6ed9' User entered 'Yes (Y)'	System	15 Sep 2020 22:59:12
	System	15 Sep 2020 22:59:12

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:58:59', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aff33a79-e7ba-408e-bcf9-50cb64ab6ed9' User entered '98.1'	System	15 Sep 2020 22:59:12
	System	15 Sep 2020 22:59:12

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:08', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aff33a79-e7ba-408e-bcf9-50cb64ab6ed9' User entered 'No (N)'	System	15 Sep 2020 22:59:12
	System	15 Sep 2020 22:59:12



US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:10', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aff33a79-e7ba-408e-bcf9-50cb64ab6ed9' User entered '15 Sep 2020 15:59'	System	15 Sep 2020 22:59:12
	System	15 Sep 2020 22:59:12

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:31:57', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '693bd97b-72cd-46d9-afdd-5d85c52769c6'	System	09 Sep 2020 16:32:21
User entered 'None (1)'	System	09 Sep 2020 16:32:21

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:03', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '693bd97b-72cd-46d9-afdd-5d85c52769c6' User entered 'No (N)'	System	09 Sep 2020 16:32:21
	System	09 Sep 2020 16:32:21

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:09', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '693bd97b-72cd-46d9-afdd-5d85c52769c6' User entered 'No (N)'	System	09 Sep 2020 16:32:21
	System	09 Sep 2020 16:32:21

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:14', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '693bd97b-72cd-46d9-afdd-5d85c52769c6'	System	09 Sep 2020 16:32:21
User entered 'None (1)'	System	09 Sep 2020 16:32:21



US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:18', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '693bd97b-72cd-46d9-afdd-5d85c52769c6' User entered '09 Sep 2020 09:32'	System	09 Sep 2020 16:32:21
	System	09 Sep 2020 16:32:21

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Sep 2020 09:09'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Sep 2020 11:39'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:16:50', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '60278a52-35c6-4409-a269-e281cf562dfd'	System	10 Sep 2020 07:17:10
User entered 'None (1)'	System	10 Sep 2020 07:17:10

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:16:53', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '60278a52-35c6-4409-a269-e281cf562dfd' User entered 'No (N)'	System	10 Sep 2020 07:17:10
	System	10 Sep 2020 07:17:10

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:16:57', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '60278a52-35c6-4409-a269-e281cf562dfd' User entered 'No (N)'	System	10 Sep 2020 07:17:10
	System	10 Sep 2020 07:17:10

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:05', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '60278a52-35c6-4409-a269-e281cf562dfd'	System	10 Sep 2020 07:17:10
User entered 'None (1)'	System	10 Sep 2020 07:17:10



US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:09', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '60278a52-35c6-4409-a269-e281cf562dfd' User entered '10 Sep 2020 00:17'	System	10 Sep 2020 07:17:10
	System	10 Sep 2020 07:17:10

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Sep 2020 12:34'	System	09 Sep 2020 16:27:40

**US3262259**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 2'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:28:53', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25120044-a4ed-4528-a8e5-a62d9944e9bd' User entered 'None (1)'	System	10 Sep 2020 22:29:19
	System	10 Sep 2020 22:29:19

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:28:57', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25120044-a4ed-4528-a8e5-a62d9944e9bd' User entered 'No (N)'	System	10 Sep 2020 22:29:19
	System	10 Sep 2020 22:29:19

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:05', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25120044-a4ed-4528-a8e5-a62d9944e9bd' User entered 'No (N)'	System	10 Sep 2020 22:29:19
	System	10 Sep 2020 22:29:19

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:13', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25120044-a4ed-4528-a8e5-a62d9944e9bd' User entered 'None (1)'	System	10 Sep 2020 22:29:19
	System	10 Sep 2020 22:29:19



**US3262259**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:17', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25120044-a4ed-4528-a8e5-a62d9944e9bd' User entered '10 Sep 2020 15:29'	System	10 Sep 2020 22:29:19
	System	10 Sep 2020 22:29:19

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

**US3262259**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 3'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:22', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0dc4e4b4-4580-47a9-934d-60d92881fd22'	System	12 Sep 2020 07:24:41
User entered 'None (1)'	System	12 Sep 2020 07:24:41

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0dc4e4b4-4580-47a9-934d-60d92881fd22'	System	12 Sep 2020 07:24:41
User entered 'No (N)'	System	12 Sep 2020 07:24:41

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:34', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0dc4e4b4-4580-47a9-934d-60d92881fd22'	System	12 Sep 2020 07:24:41
User entered 'No (N)'	System	12 Sep 2020 07:24:41

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:37', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0dc4e4b4-4580-47a9-934d-60d92881fd22'	System	12 Sep 2020 07:24:41
User entered 'None (1)'	System	12 Sep 2020 07:24:41



US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:40', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0dc4e4b4-4580-47a9-934d-60d92881fd22'	System	12 Sep 2020 07:24:41
User entered '12 Sep 2020 00:24'	System	12 Sep 2020 07:24:41

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 4'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:43', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'add9ab11-cdfc-403b-ab22-161331fe78de'	System	13 Sep 2020 02:01:57
User entered 'None (1)'	System	13 Sep 2020 02:01:57

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:46', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'add9ab11-cdfc-403b-ab22-161331fe78de' User entered 'No (N)'	System	13 Sep 2020 02:01:57
	System	13 Sep 2020 02:01:57

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:49', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'add9ab11-cdfc-403b-ab22-161331fe78de' User entered 'No (N)'	System	13 Sep 2020 02:01:57
	System	13 Sep 2020 02:01:57

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:52', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'add9ab11-cdfc-403b-ab22-161331fe78de' User entered 'None (1)'	System	13 Sep 2020 02:01:57
	System	13 Sep 2020 02:01:57



US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:55', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'add9ab11-cdfc-403b-ab22-161331fe78de' User entered '12 Sep 2020 19:01'	System	13 Sep 2020 02:01:57
	System	13 Sep 2020 02:01:57

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 5'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:31:23', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'da144d21-86ab-48f6-8248-f9c6ba35dc9a'	System	13 Sep 2020 20:32:23
User entered 'None (1)'	System	13 Sep 2020 20:32:23

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:31:34', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'da144d21-86ab-48f6-8248-f9c6ba35dc9a'	System	13 Sep 2020 20:32:23
User entered 'No (N)'	System	13 Sep 2020 20:32:23

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:31:38', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'da144d21-86ab-48f6-8248-f9c6ba35dc9a' User entered 'No (N)'	System	13 Sep 2020 20:32:23
	System	13 Sep 2020 20:32:23

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:31:56', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'da144d21-86ab-48f6-8248-f9c6ba35dc9a'	System	13 Sep 2020 20:32:23
User entered 'None (1)'	System	13 Sep 2020 20:32:23



US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:31:59', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'da144d21-86ab-48f6-8248-f9c6ba35dc9a' User entered '13 Sep 2020 13:31'	System	13 Sep 2020 20:32:23
	System	13 Sep 2020 20:32:23

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

**US3262259**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 6'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:44:51', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '205f23d2-9f26-49b1-95c8-b108a89072e0' User entered 'None (1)'	System	14 Sep 2020 19:45:12
	System	14 Sep 2020 19:45:12

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:44:54', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '205f23d2-9f26-49b1-95c8-b108a89072e0' User entered 'No (N)'	System	14 Sep 2020 19:45:12
	System	14 Sep 2020 19:45:12

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:01', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '205f23d2-9f26-49b1-95c8-b108a89072e0' User entered 'No (N)'	System	14 Sep 2020 19:45:12
	System	14 Sep 2020 19:45:12

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:05', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '205f23d2-9f26-49b1-95c8-b108a89072e0' User entered 'None (1)'	System	14 Sep 2020 19:45:12
	System	14 Sep 2020 19:45:12



**US3262259**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:08', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '205f23d2-9f26-49b1-95c8-b108a89072e0' User entered '14 Sep 2020 12:45'	System	14 Sep 2020 19:45:12
	System	14 Sep 2020 19:45:12

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

**US3262259**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 7'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:14', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'ca291152-c8f8-4701-90cf-46c485029b8f' User entered 'None (1)'	System	15 Sep 2020 22:59:32
	System	15 Sep 2020 22:59:32

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:16', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'ca291152-c8f8-4701-90cf-46c485029b8f' User entered 'No (N)'	System	15 Sep 2020 22:59:32
	System	15 Sep 2020 22:59:32

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:20', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'ca291152-c8f8-4701-90cf-46c485029b8f' User entered 'No (N)'	System	15 Sep 2020 22:59:32
	System	15 Sep 2020 22:59:32

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:23', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'ca291152-c8f8-4701-90cf-46c485029b8f' User entered 'None (1)'	System	15 Sep 2020 22:59:32
	System	15 Sep 2020 22:59:32



US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:26', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'ca291152-c8f8-4701-90cf-46c485029b8f' User entered '15 Sep 2020 15:59'	System	15 Sep 2020 22:59:32
	System	15 Sep 2020 22:59:32

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:25', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25a0a5e9-3f54-4caf-9874-f7f04cd93b24' User entered 'None (0)'	System	09 Sep 2020 16:32:55
	System	09 Sep 2020 16:32:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25a0a5e9-3f54-4caf-9874-f7f04cd93b24' User entered 'None (0)'	System	09 Sep 2020 16:32:55
	System	09 Sep 2020 16:32:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:34', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25a0a5e9-3f54-4caf-9874-f7f04cd93b24' User entered 'None (0)'	System	09 Sep 2020 16:32:55
	System	09 Sep 2020 16:32:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:38', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25a0a5e9-3f54-4caf-9874-f7f04cd93b24' User entered 'None (0)'	System	09 Sep 2020 16:32:55
	System	09 Sep 2020 16:32:55



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:41', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25a0a5e9-3f54-4caf-9874-f7f04cd93b24' User entered 'None (0)'	System	09 Sep 2020 16:32:55
	System	09 Sep 2020 16:32:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:44', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25a0a5e9-3f54-4caf-9874-f7f04cd93b24' User entered 'None (0)'	System	09 Sep 2020 16:32:55
	System	09 Sep 2020 16:32:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:49', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25a0a5e9-3f54-4caf-9874-f7f04cd93b24' User entered 'No (N)'	System	09 Sep 2020 16:32:55
	System	09 Sep 2020 16:32:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-09T09:32:53', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '25a0a5e9-3f54-4caf-9874-f7f04cd93b24' User entered '09 Sep 2020 09:32'	System	09 Sep 2020 16:32:55
	System	09 Sep 2020 16:32:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Sep 2020 09:09'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Sep 2020 11:39'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:14', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '989ad16b-ad4c-400a-a8fd-c969db0016a5' User entered 'None (0)'	System	10 Sep 2020 07:17:55
	System	10 Sep 2020 07:17:55



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:16', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '989ad16b-ad4c-400a-a8fd-c969db0016a5' User entered 'None (0)'	System	10 Sep 2020 07:17:55
	System	10 Sep 2020 07:17:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:20', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '989ad16b-ad4c-400a-a8fd-c969db0016a5' User entered 'None (0)'	System	10 Sep 2020 07:17:55
	System	10 Sep 2020 07:17:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:27', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '989ad16b-ad4c-400a-a8fd-c969db0016a5' User entered 'None (0)'	System	10 Sep 2020 07:17:55
	System	10 Sep 2020 07:17:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:42', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '989ad16b-ad4c-400a-a8fd-c969db0016a5' User entered 'None (0)'	System	10 Sep 2020 07:17:55
	System	10 Sep 2020 07:17:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:45', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '989ad16b-ad4c-400a-a8fd-c969db0016a5' User entered 'None (0)'	System	10 Sep 2020 07:17:55
	System	10 Sep 2020 07:17:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:49', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '989ad16b-ad4c-400a-a8fd-c969db0016a5' User entered 'No (N)'	System	10 Sep 2020 07:17:55
	System	10 Sep 2020 07:17:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T00:17:53', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '989ad16b-ad4c-400a-a8fd-c969db0016a5' User entered '10 Sep 2020 00:17'	System	10 Sep 2020 07:17:55
	System	10 Sep 2020 07:17:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Sep 2020 12:34'	System	09 Sep 2020 16:27:40



**US3262259**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 2'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:22', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '3bbe088f-1d2e-4169-8519-652fb46a9787' User entered 'None (0)'	System	10 Sep 2020 22:29:55
	System	10 Sep 2020 22:29:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:28', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '3bbe088f-1d2e-4169-8519-652fb46a9787' User entered 'None (0)'	System	10 Sep 2020 22:29:55
	System	10 Sep 2020 22:29:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '3bbe088f-1d2e-4169-8519-652fb46a9787' User entered 'None (0)'	System	10 Sep 2020 22:29:55
	System	10 Sep 2020 22:29:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:34', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '3bbe088f-1d2e-4169-8519-652fb46a9787' User entered 'None (0)'	System	10 Sep 2020 22:29:55
	System	10 Sep 2020 22:29:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:37', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '3bbe088f-1d2e-4169-8519-652fb46a9787' User entered 'None (0)'	System	10 Sep 2020 22:29:55
	System	10 Sep 2020 22:29:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:41', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '3bbe088f-1d2e-4169-8519-652fb46a9787' User entered 'None (0)'	System	10 Sep 2020 22:29:55
	System	10 Sep 2020 22:29:55



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:50', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '3bbe088f-1d2e-4169-8519-652fb46a9787' User entered 'No (N)'	System	10 Sep 2020 22:29:55
	System	10 Sep 2020 22:29:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-10T15:29:53', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '3bbe088f-1d2e-4169-8519-652fb46a9787' User entered '10 Sep 2020 15:29'	System	10 Sep 2020 22:29:55
	System	10 Sep 2020 22:29:55

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 3'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:44', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b835da4-7e5d-4c18-846d-67edc97d9831' User entered 'None (0)'	System	12 Sep 2020 07:25:07
	System	12 Sep 2020 07:25:07

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:46', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b835da4-7e5d-4c18-846d-67edc97d9831' User entered 'None (0)'	System	12 Sep 2020 07:25:07
	System	12 Sep 2020 07:25:07

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:49', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b835da4-7e5d-4c18-846d-67edc97d9831' User entered 'None (0)'	System	12 Sep 2020 07:25:07
	System	12 Sep 2020 07:25:07



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:51', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b835da4-7e5d-4c18-846d-67edc97d9831' User entered 'None (0)'	System	12 Sep 2020 07:25:07
	System	12 Sep 2020 07:25:07

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:55', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b835da4-7e5d-4c18-846d-67edc97d9831' User entered 'None (0)'	System	12 Sep 2020 07:25:07
	System	12 Sep 2020 07:25:07

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:24:58', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b835da4-7e5d-4c18-846d-67edc97d9831' User entered 'None (0)'	System	12 Sep 2020 07:25:07
	System	12 Sep 2020 07:25:07

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:25:03', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b835da4-7e5d-4c18-846d-67edc97d9831' User entered 'No (N)'	System	12 Sep 2020 07:25:07
	System	12 Sep 2020 07:25:07

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T00:25:06', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b835da4-7e5d-4c18-846d-67edc97d9831' User entered '12 Sep 2020 00:25'	System	12 Sep 2020 07:25:07
	System	12 Sep 2020 07:25:07

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 4'	System	09 Sep 2020 16:27:40



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:01:58', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '5bd7a4fe-0eba-4d16-8651-a4703f59c176' User entered 'None (0)'	System	13 Sep 2020 02:02:18
	System	13 Sep 2020 02:02:18

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:02:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '5bd7a4fe-0eba-4d16-8651-a4703f59c176' User entered 'None (0)'	System	13 Sep 2020 02:02:18
	System	13 Sep 2020 02:02:18

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:02:02', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '5bd7a4fe-0eba-4d16-8651-a4703f59c176' User entered 'None (0)'	System	13 Sep 2020 02:02:18
	System	13 Sep 2020 02:02:18

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:02:04', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '5bd7a4fe-0eba-4d16-8651-a4703f59c176' User entered 'None (0)'	System	13 Sep 2020 02:02:18
	System	13 Sep 2020 02:02:18

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:02:06', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '5bd7a4fe-0eba-4d16-8651-a4703f59c176' User entered 'None (0)'	System	13 Sep 2020 02:02:18
	System	13 Sep 2020 02:02:18

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:02:09', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '5bd7a4fe-0eba-4d16-8651-a4703f59c176' User entered 'None (0)'	System	13 Sep 2020 02:02:18
	System	13 Sep 2020 02:02:18

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:02:11', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '5bd7a4fe-0eba-4d16-8651-a4703f59c176' User entered 'No (N)'	System	13 Sep 2020 02:02:18
	System	13 Sep 2020 02:02:18

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-12T19:02:14', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '5bd7a4fe-0eba-4d16-8651-a4703f59c176' User entered '12 Sep 2020 19:02'	System	13 Sep 2020 02:02:18
	System	13 Sep 2020 02:02:18



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 5'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:32:17', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'bfdb2220-addf-4335-93bb-b6290fa10f6e' User entered 'None (0)'	System	13 Sep 2020 20:32:40
	System	13 Sep 2020 20:32:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:32:19', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'bfdb2220-addf-4335-93bb-b6290fa10f6e' User entered 'None (0)'	System	13 Sep 2020 20:32:40
	System	13 Sep 2020 20:32:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:32:22', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'bfdb2220-addf-4335-93bb-b6290fa10f6e' User entered 'None (0)'	System	13 Sep 2020 20:32:40
	System	13 Sep 2020 20:32:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:32:24', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'bfdb2220-addf-4335-93bb-b6290fa10f6e' User entered 'None (0)'	System	13 Sep 2020 20:32:40
	System	13 Sep 2020 20:32:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:32:26', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'bfdb2220-addf-4335-93bb-b6290fa10f6e' User entered 'None (0)'	System	13 Sep 2020 20:32:40
	System	13 Sep 2020 20:32:40



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:32:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'bfdb2220-addf-4335-93bb-b6290fa10f6e' User entered 'None (0)'	System	13 Sep 2020 20:32:40
	System	13 Sep 2020 20:32:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:32:36', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'bfdb2220-addf-4335-93bb-b6290fa10f6e' User entered 'No (N)'	System	13 Sep 2020 20:32:40
	System	13 Sep 2020 20:32:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-13T13:32:39', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'bfdb2220-addf-4335-93bb-b6290fa10f6e' User entered '13 Sep 2020 13:32'	System	13 Sep 2020 20:32:40
	System	13 Sep 2020 20:32:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

**US3262259**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 6'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:12', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '74f7894f-9ddf-48b9-8bb2-fea88d44db93' User entered 'None (0)'	System	14 Sep 2020 19:45:52
	System	14 Sep 2020 19:45:52

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:14', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '74f7894f-9ddf-48b9-8bb2-fea88d44db93' User entered 'None (0)'	System	14 Sep 2020 19:45:52
	System	14 Sep 2020 19:45:52



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:17', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '74f7894f-9ddf-48b9-8bb2-fea88d44db93' User entered 'None (0)'	System	14 Sep 2020 19:45:52
	System	14 Sep 2020 19:45:52

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:19', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '74f7894f-9ddf-48b9-8bb2-fea88d44db93' User entered 'None (0)'	System	14 Sep 2020 19:45:52
	System	14 Sep 2020 19:45:52

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:42', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '74f7894f-9ddf-48b9-8bb2-fea88d44db93'	System	14 Sep 2020 19:45:52
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	14 Sep 2020 19:45:52

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:40', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '74f7894f-9ddf-48b9-8bb2-fea88d44db93' User entered 'None (0)'	System	14 Sep 2020 19:45:52
	System	14 Sep 2020 19:45:52

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:45', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '74f7894f-9ddf-48b9-8bb2-fea88d44db93'	System	14 Sep 2020 19:45:52
User entered 'No (N)'	System	14 Sep 2020 19:45:52

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-14T12:45:49', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '74f7894f-9ddf-48b9-8bb2-fea88d44db93'	System	14 Sep 2020 19:45:52
User entered '14 Sep 2020 12:45'	System	14 Sep 2020 19:45:52

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

**US3262259**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:27:40



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 7'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '83326102-71f6-4b4b-920e-a75aca6b6fb7' User entered 'None (0)'	System	15 Sep 2020 22:59:50
	System	15 Sep 2020 22:59:50

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:34', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '83326102-71f6-4b4b-920e-a75aca6b6fb7' User entered 'None (0)'	System	15 Sep 2020 22:59:50
	System	15 Sep 2020 22:59:50

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:36', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '83326102-71f6-4b4b-920e-a75aca6b6fb7' User entered 'None (0)'	System	15 Sep 2020 22:59:50
	System	15 Sep 2020 22:59:50

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:38', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '83326102-71f6-4b4b-920e-a75aca6b6fb7' User entered 'None (0)'	System	15 Sep 2020 22:59:50
	System	15 Sep 2020 22:59:50

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:40', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '83326102-71f6-4b4b-920e-a75aca6b6fb7' User entered 'None (0)'	System	15 Sep 2020 22:59:50
	System	15 Sep 2020 22:59:50

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:41', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '83326102-71f6-4b4b-920e-a75aca6b6fb7' User entered 'None (0)'	System	15 Sep 2020 22:59:50
	System	15 Sep 2020 22:59:50

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:44', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '83326102-71f6-4b4b-920e-a75aca6b6fb7'	System	15 Sep 2020 22:59:50
User entered 'No (N)'	System	15 Sep 2020 22:59:50



US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42CDED06-9603-4CAE-82C3-D502C1DCC06D)', Time: '2020-09-15T15:59:46', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '83326102-71f6-4b4b-920e-a75aca6b6fb7'	System	15 Sep 2020 22:59:50
User entered '15 Sep 2020 15:59'	System	15 Sep 2020 22:59:50

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:27:40

US3262259

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:27:40

**US3262259**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:30:26

**US3262259**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:30:26

**US3262259**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:30:26

**US3262259**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:30:26

**US3262259**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:30:33



**US3262259**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	05 Oct 2020 14:30:33

**US3262259**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:09

**US3262259**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:09

**US3262259**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:09

US3262259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:09

**US3262259**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:15

US3262259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	05 Oct 2020 14:31:15

**US3262259**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:41



**US3262259**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:41

**US3262259**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:41

**US3262259**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:41

US3262259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:31:49

**US3262259**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	05 Oct 2020 14:31:49

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:56:43

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:56:43

US3262259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:56:43



**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'VISIT2'	System	08 Oct 2020 14:56:43

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User accepted default value 'Pre-Dose (PREDOSE)'		08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09:38'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '07 Oct 2020 09:38'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41



**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '67'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'bpm'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '14'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'breaths/min'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '139'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '97'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41



US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User accepted default value 'Post-Dose (POSTDOSE)'		08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '11:43'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '07 Oct 2020 11:43'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41



**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '79'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'bpm'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '14'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'breaths/min'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '136'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '98'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:41



US3262259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	08 Oct 2020 14:58:41

US3262259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:59

US3262259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:58:59

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:45:33

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:45:33

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:45:33

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 18:45:33

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:45:33



US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '10:43'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:45:33

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '07 Oct 2020 10:43'	System	07 Oct 2020 18:45:33

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:45:33

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'ONCE'	System	07 Oct 2020 18:45:33

US3262259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 18:45:33

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:24

US3262259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:24

US3262259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:19:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09:51'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:24



**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '07 Oct 2020 09:51'	System	08 Oct 2020 14:59:24

US3262259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:48

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		08 Oct 2020 14:59:48

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:48

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09:40'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:48

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '07 Oct 2020 09:40'	System	08 Oct 2020 14:59:48

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		08 Oct 2020 14:59:48

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:48



**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:48

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered empty.	System	08 Oct 2020 14:59:48

US3262259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:59:56

**US3262259**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	08 Oct 2020 14:59:56

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:47:54', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e8c9e824-d48e-426f-9820-c069b9f47f5a' User entered 'Yes (Y)'	System	07 Oct 2020 18:48:41
	System	07 Oct 2020 18:48:41

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e8c9e824-d48e-426f-9820-c069b9f47f5a' User entered '98.0'	System	07 Oct 2020 18:48:41
	System	07 Oct 2020 18:48:41

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:04', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e8c9e824-d48e-426f-9820-c069b9f47f5a' User entered 'No (N)'	System	07 Oct 2020 18:48:41
	System	07 Oct 2020 18:48:41



US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:08', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e8c9e824-d48e-426f-9820-c069b9f47f5a' User entered '07 Oct 2020 11:48'	System	07 Oct 2020 18:48:41
	System	07 Oct 2020 18:48:41

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '07 Oct 2020 11:03'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '07 Oct 2020 13:33'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:06:57', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'fe55a035-05ca-4749-882e-1458d243085b' User entered 'Yes (Y)'	System	08 Oct 2020 07:07:18
	System	08 Oct 2020 07:07:18

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:04', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'fe55a035-05ca-4749-882e-1458d243085b' User entered '96.5'	System	08 Oct 2020 07:07:18
	System	08 Oct 2020 07:07:18

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:09', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'fe55a035-05ca-4749-882e-1458d243085b' User entered 'No (N)'	System	08 Oct 2020 07:07:18
	System	08 Oct 2020 07:07:18

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:15', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'fe55a035-05ca-4749-882e-1458d243085b' User entered '08 Oct 2020 00:07'	System	08 Oct 2020 07:07:18
	System	08 Oct 2020 07:07:18



US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '07 Oct 2020 14:28'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 2'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:24:16', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '06844461-6a85-4223-852f-59910bbf74d3' User entered 'Yes (Y)'	System	09 Oct 2020 00:25:17
	System	09 Oct 2020 00:25:17

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:24:54', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '06844461-6a85-4223-852f-59910bbf74d3' User entered '97.5'	System	09 Oct 2020 00:25:17
	System	09 Oct 2020 00:25:17

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:25:11', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '06844461-6a85-4223-852f-59910bbf74d3' User entered 'No (N)'	System	09 Oct 2020 00:25:17
	System	09 Oct 2020 00:25:17

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:25:13', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '06844461-6a85-4223-852f-59910bbf74d3' User entered '08 Oct 2020 17:25'	System	09 Oct 2020 00:25:17
	System	09 Oct 2020 00:25:17

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 3'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:28:23', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '174bfc47-5ed8-46f4-aae9-4da96ddfa66b' User entered 'Yes (Y)'	System	10 Oct 2020 03:28:40
	System	10 Oct 2020 03:28:40

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:28:27', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '174bfc47-5ed8-46f4-aae9-4da96ddfa66b' User entered '97.0'	System	10 Oct 2020 03:28:40
	System	10 Oct 2020 03:28:40

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:28:30', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '174bfc47-5ed8-46f4-aae9-4da96ddfa66b'	System	10 Oct 2020 03:28:40
User entered 'No (N)'	System	10 Oct 2020 03:28:40

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:28:34', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '174bfc47-5ed8-46f4-aae9-4da96ddfa66b' User entered '09 Oct 2020 20:28'	System	10 Oct 2020 03:28:40
	System	10 Oct 2020 03:28:40

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 4'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:06', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '73813305-96e1-4a4e-af8e-316dd05cdf49' User entered 'Yes (Y)'	System	11 Oct 2020 12:10:20
	System	11 Oct 2020 12:10:20

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:13', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '73813305-96e1-4a4e-af8e-316dd05cdf49' User entered '98.0'	System	11 Oct 2020 12:10:20
	System	11 Oct 2020 12:10:20

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:16', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '73813305-96e1-4a4e-af8e-316dd05cdf49'	System	11 Oct 2020 12:10:20
User entered 'No (N)'	System	11 Oct 2020 12:10:20

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:19', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '73813305-96e1-4a4e-af8e-316dd05cdf49'	System	11 Oct 2020 12:10:20
User entered '11 Oct 2020 05:10'	System	11 Oct 2020 12:10:20

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 5'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 6'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:43:46', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aae57cd3-874f-4927-a16a-ecab86012e08' User entered 'Yes (Y)'	System	13 Oct 2020 14:44:07
	System	13 Oct 2020 14:44:07

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:43:54', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aae57cd3-874f-4927-a16a-ecab86012e08' User entered '98.1'	System	13 Oct 2020 14:44:07
	System	13 Oct 2020 14:44:07

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:43:57', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aae57cd3-874f-4927-a16a-ecab86012e08'	System	13 Oct 2020 14:44:07
User entered 'No (N)'	System	13 Oct 2020 14:44:07

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'aae57cd3-874f-4927-a16a-ecab86012e08' User entered '13 Oct 2020 07:44'	System	13 Oct 2020 14:44:07
	System	13 Oct 2020 14:44:07

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 7'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:18', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd8fa3e3c-3fb4-4858-a171-c527312ebb82'	System	13 Oct 2020 22:31:38
User entered 'Yes (Y)'	System	13 Oct 2020 22:31:38

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:23', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd8fa3e3c-3fb4-4858-a171-c527312ebb82' User entered '97.5'	System	13 Oct 2020 22:31:38
	System	13 Oct 2020 22:31:38

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd8fa3e3c-3fb4-4858-a171-c527312ebb82'	System	13 Oct 2020 22:31:38
User entered 'No (N)'	System	13 Oct 2020 22:31:38

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:35', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd8fa3e3c-3fb4-4858-a171-c527312ebb82' User entered '13 Oct 2020 15:31'	System	13 Oct 2020 22:31:38
	System	13 Oct 2020 22:31:38

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:14', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'fee9642-a6e4-465d-a5fb-8c6b7025b3e8'	System	07 Oct 2020 18:48:46
User entered 'None (1)'	System	07 Oct 2020 18:48:46



US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:20', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'fee9642-a6e4-465d-a5fb-8c6b7025b3e8'	System	07 Oct 2020 18:48:46
User entered 'No (N)'	System	07 Oct 2020 18:48:46

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:26', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'fee9642-a6e4-465d-a5fb-8c6b7025b3e8'	System	07 Oct 2020 18:48:46
User entered 'No (N)'	System	07 Oct 2020 18:48:46

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:30', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'fee9642-a6e4-465d-a5fb-8c6b7025b3e8'	System	07 Oct 2020 18:48:46
User entered 'None (1)'	System	07 Oct 2020 18:48:46

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:33', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'fee9642-a6e4-465d-a5fb-8c6b7025b3e8' User entered '07 Oct 2020 11:48'	System	07 Oct 2020 18:48:46
	System	07 Oct 2020 18:48:46

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '07 Oct 2020 11:03'	System	07 Oct 2020 18:45:33

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '07 Oct 2020 13:33'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:23', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '537745ee-9bda-4fa0-9964-3cd0264d2775' User entered 'None (1)'	System	08 Oct 2020 07:07:45
	System	08 Oct 2020 07:07:45



US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:27', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '537745ee-9bda-4fa0-9964-3cd0264d2775' User entered 'No (N)'	System	08 Oct 2020 07:07:45
	System	08 Oct 2020 07:07:45

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:33', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '537745ee-9bda-4fa0-9964-3cd0264d2775' User entered 'No (N)'	System	08 Oct 2020 07:07:45
	System	08 Oct 2020 07:07:45

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:37', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '537745ee-9bda-4fa0-9964-3cd0264d2775' User entered 'None (1)'	System	08 Oct 2020 07:07:45
	System	08 Oct 2020 07:07:45

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:40', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '537745ee-9bda-4fa0-9964-3cd0264d2775' User entered '08 Oct 2020 00:07'	System	08 Oct 2020 07:07:45
	System	08 Oct 2020 07:07:45

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '07 Oct 2020 14:28'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 2'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:25:17', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0ebb6b84-d21f-46cf-9713-f333395699bc' User entered 'None (1)'	System	09 Oct 2020 00:25:45
	System	09 Oct 2020 00:25:45



US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:25:21', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0ebb6b84-d21f-46cf-9713-f333395699bc' User entered 'No (N)'	System	09 Oct 2020 00:25:45
	System	09 Oct 2020 00:25:45

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:25:28', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0ebb6b84-d21f-46cf-9713-f333395699bc' User entered 'No (N)'	System	09 Oct 2020 00:25:45
	System	09 Oct 2020 00:25:45

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:25:38', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0ebb6b84-d21f-46cf-9713-f333395699bc' User entered 'None (1)'	System	09 Oct 2020 00:25:45
	System	09 Oct 2020 00:25:45

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:25:41', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '0ebb6b84-d21f-46cf-9713-f333395699bc' User entered '08 Oct 2020 17:25'	System	09 Oct 2020 00:25:45
	System	09 Oct 2020 00:25:45

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 3'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:28:39', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8a30ec7a-fa0c-4fe3-9cfb-30faf731efc7'	System	10 Oct 2020 03:29:03
User entered 'None (1)'	System	10 Oct 2020 03:29:03



US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:28:48', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8a30ec7a-fa0c-4fe3-9cfb-30faf731efc7'	System	10 Oct 2020 03:29:03
User entered 'No (N)'	System	10 Oct 2020 03:29:03

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:28:53', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8a30ec7a-fa0c-4fe3-9cfb-30faf731efc7'	System	10 Oct 2020 03:29:03
User entered 'No (N)'	System	10 Oct 2020 03:29:03

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:28:58', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8a30ec7a-fa0c-4fe3-9cfb-30faf731efc7'	System	10 Oct 2020 03:29:03
User entered 'None (1)'	System	10 Oct 2020 03:29:03

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:29:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8a30ec7a-fa0c-4fe3-9cfb-30faf731efc7' User entered '09 Oct 2020 20:29'	System	10 Oct 2020 03:29:03
	System	10 Oct 2020 03:29:03

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 4'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:22', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '4fde3bad-d7f3-4a85-be86-2f13d0b12d0a'	System	11 Oct 2020 12:10:34
User entered 'None (1)'	System	11 Oct 2020 12:10:34



US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:24', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '4fde3bad-d7f3-4a85-be86-2f13d0b12d0a' User entered 'No (N)'	System	11 Oct 2020 12:10:34
	System	11 Oct 2020 12:10:34

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:27', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '4fde3bad-d7f3-4a85-be86-2f13d0b12d0a'	System	11 Oct 2020 12:10:34
User entered 'No (N)'	System	11 Oct 2020 12:10:34

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:29', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '4fde3bad-d7f3-4a85-be86-2f13d0b12d0a'	System	11 Oct 2020 12:10:34
User entered 'None (1)'	System	11 Oct 2020 12:10:34

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:32', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '4fde3bad-d7f3-4a85-be86-2f13d0b12d0a' User entered '11 Oct 2020 05:10'	System	11 Oct 2020 12:10:34
	System	11 Oct 2020 12:10:34

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 5'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32



US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 6'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:05', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'af304ea9-5016-4930-b67e-a766ac0f263f' User entered 'None (1)'	System	13 Oct 2020 14:44:27
	System	13 Oct 2020 14:44:27

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:12', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'af304ea9-5016-4930-b67e-a766ac0f263f' User entered 'No (N)'	System	13 Oct 2020 14:44:27
	System	13 Oct 2020 14:44:27

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:15', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'af304ea9-5016-4930-b67e-a766ac0f263f' User entered 'No (N)'	System	13 Oct 2020 14:44:27
	System	13 Oct 2020 14:44:27

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:18', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'af304ea9-5016-4930-b67e-a766ac0f263f' User entered 'None (1)'	System	13 Oct 2020 14:44:27
	System	13 Oct 2020 14:44:27

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:21', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'af304ea9-5016-4930-b67e-a766ac0f263f' User entered '13 Oct 2020 07:44'	System	13 Oct 2020 14:44:27
	System	13 Oct 2020 14:44:27

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 7'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:39', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '1eda1d0b-eec0-4b5c-9f95-d5fe0ec36d82'	System	13 Oct 2020 22:31:54
User entered 'None (1)'	System	13 Oct 2020 22:31:54

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:42', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '1eda1d0b-eec0-4b5c-9f95-d5fe0ec36d82'	System	13 Oct 2020 22:31:54
User entered 'No (N)'	System	13 Oct 2020 22:31:54

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:44', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '1eda1d0b-eec0-4b5c-9f95-d5fe0ec36d82'	System	13 Oct 2020 22:31:54
User entered 'No (N)'	System	13 Oct 2020 22:31:54

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:47', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '1eda1d0b-eec0-4b5c-9f95-d5fe0ec36d82'	System	13 Oct 2020 22:31:54
User entered 'None (1)'	System	13 Oct 2020 22:31:54

US3262259

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:51', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '1eda1d0b-eec0-4b5c-9f95-d5fe0ec36d82'	System	13 Oct 2020 22:31:54
User entered '13 Oct 2020 15:31'	System	13 Oct 2020 22:31:54

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:42', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e14e8c37-fc60-40f6-96c7-6c3d6c51b7e7' User entered 'None (0)'	System	07 Oct 2020 18:49:14
	System	07 Oct 2020 18:49:14

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:46', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e14e8c37-fc60-40f6-96c7-6c3d6c51b7e7' User entered 'None (0)'	System	07 Oct 2020 18:49:14
	System	07 Oct 2020 18:49:14

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:49', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e14e8c37-fc60-40f6-96c7-6c3d6c51b7e7' User entered 'None (0)'	System	07 Oct 2020 18:49:14
	System	07 Oct 2020 18:49:14

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:54', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e14e8c37-fc60-40f6-96c7-6c3d6c51b7e7' User entered 'None (0)'	System	07 Oct 2020 18:49:14
	System	07 Oct 2020 18:49:14

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:48:57', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e14e8c37-fc60-40f6-96c7-6c3d6c51b7e7' User entered 'None (0)'	System	07 Oct 2020 18:49:14
	System	07 Oct 2020 18:49:14

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:49:01', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e14e8c37-fc60-40f6-96c7-6c3d6c51b7e7' User entered 'None (0)'	System	07 Oct 2020 18:49:14
	System	07 Oct 2020 18:49:14

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:49:06', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e14e8c37-fc60-40f6-96c7-6c3d6c51b7e7'	System	07 Oct 2020 18:49:14
User entered 'No (N)'	System	07 Oct 2020 18:49:14



**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-07T11:49:09', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e14e8c37-fc60-40f6-96c7-6c3d6c51b7e7' User entered '07 Oct 2020 11:49'	System	07 Oct 2020 18:49:14
	System	07 Oct 2020 18:49:14

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '07 Oct 2020 11:03'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '07 Oct 2020 13:33'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 18:45:33

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:19:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:50', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5d2a043-6805-4791-9000-ded01b01e241' User entered 'None (0)'	System	08 Oct 2020 07:08:17
	System	08 Oct 2020 07:08:17

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:53', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5d2a043-6805-4791-9000-ded01b01e241' User entered 'None (0)'	System	08 Oct 2020 07:08:17
	System	08 Oct 2020 07:08:17

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:07:57', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5d2a043-6805-4791-9000-ded01b01e241' User entered 'None (0)'	System	08 Oct 2020 07:08:17
	System	08 Oct 2020 07:08:17

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:08:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5d2a043-6805-4791-9000-ded01b01e241' User entered 'None (0)'	System	08 Oct 2020 07:08:17
	System	08 Oct 2020 07:08:17



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:08:04', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5d2a043-6805-4791-9000-ded01b01e241' User entered 'None (0)'	System	08 Oct 2020 07:08:17
	System	08 Oct 2020 07:08:17

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:08:07', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5d2a043-6805-4791-9000-ded01b01e241' User entered 'None (0)'	System	08 Oct 2020 07:08:17
	System	08 Oct 2020 07:08:17

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:08:10', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5d2a043-6805-4791-9000-ded01b01e241' User entered 'No (N)'	System	08 Oct 2020 07:08:17
	System	08 Oct 2020 07:08:17

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T00:08:13', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5d2a043-6805-4791-9000-ded01b01e241' User entered '08 Oct 2020 00:08'	System	08 Oct 2020 07:08:17
	System	08 Oct 2020 07:08:17

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '07 Oct 2020 14:28'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 2'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:26:03', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '66d70d92-23ec-4c67-968f-1ccf7a32e7cd'	System	09 Oct 2020 00:26:28
User entered 'No interference with activity (1)'	System	09 Oct 2020 00:26:28



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:26:06', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '66d70d92-23ec-4c67-968f-1ccf7a32e7cd' User entered 'None (0)'	System	09 Oct 2020 00:26:28
	System	09 Oct 2020 00:26:28

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:26:13', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '66d70d92-23ec-4c67-968f-1ccf7a32e7cd' User entered 'None (0)'	System	09 Oct 2020 00:26:28
	System	09 Oct 2020 00:26:28

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:26:16', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '66d70d92-23ec-4c67-968f-1ccf7a32e7cd' User entered 'None (0)'	System	09 Oct 2020 00:26:28
	System	09 Oct 2020 00:26:28

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:26:18', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '66d70d92-23ec-4c67-968f-1ccf7a32e7cd' User entered 'None (0)'	System	09 Oct 2020 00:26:28
	System	09 Oct 2020 00:26:28

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:26:20', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '66d70d92-23ec-4c67-968f-1ccf7a32e7cd' User entered 'None (0)'	System	09 Oct 2020 00:26:28
	System	09 Oct 2020 00:26:28

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:26:23', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '66d70d92-23ec-4c67-968f-1ccf7a32e7cd' User entered 'No (N)'	System	09 Oct 2020 00:26:28
	System	09 Oct 2020 00:26:28

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-08T17:26:26', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '66d70d92-23ec-4c67-968f-1ccf7a32e7cd' User entered '08 Oct 2020 17:26'	System	09 Oct 2020 00:26:28
	System	09 Oct 2020 00:26:28

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 3'	System	07 Oct 2020 18:45:33

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:19:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:29:04', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '10e7d856-749a-47a6-98e9-4ab1ff37f0e5' User entered 'None (0)'	System	10 Oct 2020 03:29:24
	System	10 Oct 2020 03:29:24

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:19:44**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:29:06', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '10e7d856-749a-47a6-98e9-4ab1ff37f0e5' User entered 'None (0)'	System	10 Oct 2020 03:29:24
	System	10 Oct 2020 03:29:24

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:29:08', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '10e7d856-749a-47a6-98e9-4ab1ff37f0e5' User entered 'None (0)'	System	10 Oct 2020 03:29:24
	System	10 Oct 2020 03:29:24

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:29:10', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '10e7d856-749a-47a6-98e9-4ab1ff37f0e5' User entered 'None (0)'	System	10 Oct 2020 03:29:24
	System	10 Oct 2020 03:29:24

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:29:12', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '10e7d856-749a-47a6-98e9-4ab1ff37f0e5' User entered 'None (0)'	System	10 Oct 2020 03:29:24
	System	10 Oct 2020 03:29:24

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:19:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:29:14', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '10e7d856-749a-47a6-98e9-4ab1ff37f0e5' User entered 'None (0)'	System	10 Oct 2020 03:29:24
	System	10 Oct 2020 03:29:24



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:29:18', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '10e7d856-749a-47a6-98e9-4ab1ff37f0e5' User entered 'No (N)'	System	10 Oct 2020 03:29:24
	System	10 Oct 2020 03:29:24

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-09T20:29:21', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '10e7d856-749a-47a6-98e9-4ab1ff37f0e5' User entered '09 Oct 2020 20:29'	System	10 Oct 2020 03:29:24
	System	10 Oct 2020 03:29:24

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 4'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:35', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c55f2d11-ef9f-48b2-9e8a-9b983bad423d' User entered 'None (0)'	System	11 Oct 2020 12:10:49
	System	11 Oct 2020 12:10:49

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:37', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c55f2d11-ef9f-48b2-9e8a-9b983bad423d' User entered 'None (0)'	System	11 Oct 2020 12:10:49
	System	11 Oct 2020 12:10:49

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:38', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c55f2d11-ef9f-48b2-9e8a-9b983bad423d' User entered 'None (0)'	System	11 Oct 2020 12:10:49
	System	11 Oct 2020 12:10:49



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:40', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c55f2d11-ef9f-48b2-9e8a-9b983bad423d' User entered 'None (0)'	System	11 Oct 2020 12:10:49
	System	11 Oct 2020 12:10:49

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:41', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c55f2d11-ef9f-48b2-9e8a-9b983bad423d' User entered 'None (0)'	System	11 Oct 2020 12:10:49
	System	11 Oct 2020 12:10:49

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:43', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c55f2d11-ef9f-48b2-9e8a-9b983bad423d' User entered 'None (0)'	System	11 Oct 2020 12:10:49
	System	11 Oct 2020 12:10:49

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:45', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c55f2d11-ef9f-48b2-9e8a-9b983bad423d' User entered 'No (N)'	System	11 Oct 2020 12:10:49
	System	11 Oct 2020 12:10:49

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-11T05:10:47', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c55f2d11-ef9f-48b2-9e8a-9b983bad423d' User entered '11 Oct 2020 05:10'	System	11 Oct 2020 12:10:49
	System	11 Oct 2020 12:10:49

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 5'	System	07 Oct 2020 18:45:33



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:19:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 6'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:26', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f6afea66-2de5-4bf3-934e-d3cb027ec832' User entered 'None (0)'	System	13 Oct 2020 14:44:45
	System	13 Oct 2020 14:44:45

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:29', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f6afea66-2de5-4bf3-934e-d3cb027ec832' User entered 'None (0)'	System	13 Oct 2020 14:44:45
	System	13 Oct 2020 14:44:45

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f6afea66-2de5-4bf3-934e-d3cb027ec832' User entered 'None (0)'	System	13 Oct 2020 14:44:45
	System	13 Oct 2020 14:44:45

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:33', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f6afea66-2de5-4bf3-934e-d3cb027ec832' User entered 'None (0)'	System	13 Oct 2020 14:44:45
	System	13 Oct 2020 14:44:45

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:35', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f6afea66-2de5-4bf3-934e-d3cb027ec832' User entered 'None (0)'	System	13 Oct 2020 14:44:45
	System	13 Oct 2020 14:44:45



**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:19:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:37', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f6afea66-2de5-4bf3-934e-d3cb027ec832' User entered 'None (0)'	System	13 Oct 2020 14:44:45
	System	13 Oct 2020 14:44:45

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:39', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f6afea66-2de5-4bf3-934e-d3cb027ec832' User entered 'No (N)'	System	13 Oct 2020 14:44:45
	System	13 Oct 2020 14:44:45

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T07:44:42', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f6afea66-2de5-4bf3-934e-d3cb027ec832' User entered '13 Oct 2020 07:44'	System	13 Oct 2020 14:44:45
	System	13 Oct 2020 14:44:45

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	07 Oct 2020 18:45:33
User entered 'Day 7'	System	07 Oct 2020 18:45:33

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:55', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e08e5051-29a6-476a-80f7-e17c0cb245dd' User entered 'None (0)'	System	13 Oct 2020 22:32:12
	System	13 Oct 2020 22:32:12

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:19:44**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:57', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e08e5051-29a6-476a-80f7-e17c0cb245dd' User entered 'None (0)'	System	13 Oct 2020 22:32:12
	System	13 Oct 2020 22:32:12



US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:31:59', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e08e5051-29a6-476a-80f7-e17c0cb245dd' User entered 'None (0)'	System	13 Oct 2020 22:32:12
	System	13 Oct 2020 22:32:12

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:32:01', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e08e5051-29a6-476a-80f7-e17c0cb245dd' User entered 'None (0)'	System	13 Oct 2020 22:32:12
	System	13 Oct 2020 22:32:12

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:19:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:32:03', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e08e5051-29a6-476a-80f7-e17c0cb245dd' User entered 'None (0)'	System	13 Oct 2020 22:32:12
	System	13 Oct 2020 22:32:12

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:32:05', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e08e5051-29a6-476a-80f7-e17c0cb245dd' User entered 'None (0)'	System	13 Oct 2020 22:32:12
	System	13 Oct 2020 22:32:12

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:32:06', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e08e5051-29a6-476a-80f7-e17c0cb245dd' User entered 'No (N)'	System	13 Oct 2020 22:32:12
	System	13 Oct 2020 22:32:12

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-10-13T15:32:09', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'e08e5051-29a6-476a-80f7-e17c0cb245dd' User entered '13 Oct 2020 15:32'	System	13 Oct 2020 22:32:12
	System	13 Oct 2020 22:32:12

US3262259

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 18:45:33

**US3262259**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:19:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 18:45:33



**US3262259**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	22 Oct 2020 22:00:49

**US3262259**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '14 Oct 2020'	(b) (4) Daisy Langarica (b) (4) (b) (4)	22 Oct 2020 22:00:49

**US3262259**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	22 Oct 2020 22:00:49

US3262259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) Daisy Langarica (b) (4)	22 Oct 2020 22:00:49
	(b) (4)	

US3262259

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	22 Oct 2020 22:00:53

**US3262259**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	22 Oct 2020 22:00:53

**US3262259**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	22 Oct 2020 22:04:21

**US3262259**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '22 Oct 2020'	(b) (4) Daisy Langarica (b) (4) (b) (4)	22 Oct 2020 22:04:21



**US3262259**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	22 Oct 2020 22:04:21

US3262259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) Daisy Langarica (b) (4)	22 Oct 2020 22:04:21
	(b) (4)	

US3262259

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langerica (b) (4)	22 Oct 2020 22:04:29

**US3262259**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	22 Oct 2020 22:04:29

**US3262259**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	29 Oct 2020 22:47:35

**US3262259**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '29 Oct 2020'	(b) (4) Daisy Langarica (b) (4) (b) (4)	29 Oct 2020 22:47:35

**US3262259**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	29 Oct 2020 22:47:35

US3262259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) Daisy Langarica (b) (4)	29 Oct 2020 22:47:35
	(b) (4)	



US3262259

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	29 Oct 2020 22:47:39

**US3262259**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	29 Oct 2020 22:47:39

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Nov 2020 17:34:08

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '10 Nov 2020'	(b) (4) Daisy Langarica (b) (4)	10 Nov 2020 17:34:08
	(b) (4)	

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langerica (b) (4) (b) (4)	10 Nov 2020 17:34:08

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'VISIT3'	System	10 Nov 2020 17:34:08

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langerica (b) (4)	10 Nov 2020 17:34:58

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '10 Nov 2020'	(b) (4) Daisy Langarica (b) (4)	10 Nov 2020 17:34:58
	(b) (4)	



US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09:05'	(b) (4) Daisy Langarica (b) (4)	10 Nov 2020 17:34:58
	(b) (4)	

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '10 Nov 2020 09:05'	System	10 Nov 2020 17:34:58

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '97.5' F	(b) (4) Daisy Langarica (b) (4)	10 Nov 2020 17:34:58

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	10 Nov 2020 17:34:58
	(b) (4)	

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) Daisy Langarica (b) (4) (b) (4)	10 Nov 2020 17:34:58

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '74'	(b) (4) Daisy Langarica (b) (4) (b) (4)	10 Nov 2020 17:34:58

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'bpm'	System	10 Nov 2020 17:34:58

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '12'	(b) (4) Daisy Langarica (b) (4) (b) (4)	10 Nov 2020 17:34:58



US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'breaths/min'	System	10 Nov 2020 17:34:58

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '114'	(b) (4) Daisy Langarica (b) (4) (b) (4)	10 Nov 2020 17:34:58

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	10 Nov 2020 17:34:58

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '74'	(b) (4) Daisy Langerica (b) (4) (b) (4)	10 Nov 2020 17:34:58

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'mmHg'	System	10 Nov 2020 17:34:58

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12

US3262259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12

US3262259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'No (N)'	(b) (4) Daisy Langerica (b) (4)	10 Nov 2020 17:35:28



US3262259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered empty.	(b) (4) Daisy Langerica (b) (4)	10 Nov 2020 17:35:28

US3262259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langerica (b) (4)	10 Nov 2020 21:19:19

US3262259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:19:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '10 Nov 2020'	(b) (4) Daisy Langarica (b) (4)	10 Nov 2020 21:19:19
	(b) (4)	

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered '09:10'	(b) (4) Daisy Langerica (b) (4) (b) (4)	10 Nov 2020 21:19:19

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered '10 Nov 2020 09:10'	System	10 Nov 2020 21:19:19

US3262259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	13 Feb 2021 00:18:29
User entered 'Yes (Y)'	(b) (4) Daisy Langerica (b) (4) (b) (4)	10 Nov 2020 21:19:25

**US3262259**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	10 Nov 2020 21:19:25

US3262259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 64'	System	09 Sep 2020 16:27:40



US3262259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

[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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-10T21:27:11', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'dcb733af-1270-4fa9-bb8f-02570fa05546'	System	11 Nov 2020 05:27:26
User entered 'No (N)'	System	11 Nov 2020 05:27:26

US3262259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

Have you been exposed to someone with 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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-10T21:27:17', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'dcb733af-1270-4fa9-bb8f-02570fa05546'	System	11 Nov 2020 05:27:26
User entered 'No (N)'	System	11 Nov 2020 05:27:26

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-10T21:27:22', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'dcb733af-1270-4fa9-bb8f-02570fa05546' User entered '10 Nov 2020 21:27:22'	System	11 Nov 2020 05:27:26
	System	11 Nov 2020 05:27:26

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 16:27:40

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 16:27:40

US3262259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered 'Day 71'	System	09 Sep 2020 16:27:40

US3262259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

[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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-16T04:31:16', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '01023c56-8d4d-429e-8ca2-babd44edcf7d' User entered 'No (N)'	System	16 Nov 2020 12:31:34
	System	16 Nov 2020 12:31:34

US3262259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:19:44

Have you been exposed to someone with 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 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-16T04:31:22', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '01023c56-8d4d-429e-8ca2-babd44edcf7d'	System	16 Nov 2020 12:31:34
User entered 'No (N)'	System	16 Nov 2020 12:31:34



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-16T04:31:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '01023c56-8d4d-429e-8ca2-babd44edcf7d' User entered '16 Nov 2020 04:31:31'	System	16 Nov 2020 12:31:34
	System	16 Nov 2020 12:31:34

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 16:27:40

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:35:32
Data entry locked.	System	09 Sep 2020 16:27:40
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 16:27:40

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-23T15:10:50', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '143d9777-59fa-4455-891a-f90292597e01' User entered 'No (N)'	System	23 Nov 2020 23:11:05
	System	23 Nov 2020 23:11:05

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-23T15:10:57', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '143d9777-59fa-4455-891a-f90292597e01'	System	23 Nov 2020 23:11:05
User entered 'No (N)'	System	23 Nov 2020 23:11:05

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-23T15:11:02', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '143d9777-59fa-4455-891a-f90292597e01' User entered '23 Nov 2020 15:11:02'	System	23 Nov 2020 23:11:05
	System	23 Nov 2020 23:11:05

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-29T03:06:37', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '344b2c1f-1e45-4d4c-9ac4-f3af90121e07'	System	29 Nov 2020 11:06:56
User entered 'No (N)'	System	29 Nov 2020 11:06:56

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-29T03:06:50', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '344b2c1f-1e45-4d4c-9ac4-f3af90121e07'	System	29 Nov 2020 11:06:56
User entered 'No (N)'	System	29 Nov 2020 11:06:56

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-11-29T03:06:53', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '344b2c1f-1e45-4d4c-9ac4-f3af90121e07' User entered '29 Nov 2020 03:06:53'	System	29 Nov 2020 11:06:56
	System	29 Nov 2020 11:06:56

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-07T17:59:36', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c4300c20-7cd5-4009-ac3e-85bd92097794'	System	08 Dec 2020 01:59:45
User entered 'No (N)'	System	08 Dec 2020 01:59:45

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-07T17:59:39', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c4300c20-7cd5-4009-ac3e-85bd92097794'	System	08 Dec 2020 01:59:45
User entered 'No (N)'	System	08 Dec 2020 01:59:45

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-07T17:59:42', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c4300c20-7cd5-4009-ac3e-85bd92097794' User entered '07 Dec 2020 17:59:42'	System	08 Dec 2020 01:59:45
	System	08 Dec 2020 01:59:45

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-14T19:05:40', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '224f25bf-2828-4a15-9781-52c38d4e75fc' User entered 'No (N)'	System	15 Dec 2020 03:05:49
	System	15 Dec 2020 03:05:49

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-14T19:05:43', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '224f25bf-2828-4a15-9781-52c38d4e75fc' User entered 'No (N)'	System	15 Dec 2020 03:05:49
	System	15 Dec 2020 03:05:49



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-14T19:05:46', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '224f25bf-2828-4a15-9781-52c38d4e75fc' User entered '14 Dec 2020 19:05:46'	System	15 Dec 2020 03:05:49
	System	15 Dec 2020 03:05:49

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-20T12:00:34', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b0ca01b-c0a3-4470-b838-997e9fa1c391'	System	20 Dec 2020 20:00:48
User entered 'No (N)'	System	20 Dec 2020 20:00:48

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-20T12:00:41', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b0ca01b-c0a3-4470-b838-997e9fa1c391'	System	20 Dec 2020 20:00:48
User entered 'No (N)'	System	20 Dec 2020 20:00:48

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-20T12:00:45', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '8b0ca01b-c0a3-4470-b838-997e9fa1c391' User entered '20 Dec 2020 12:00:45'	System	20 Dec 2020 20:00:48
	System	20 Dec 2020 20:00:48

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-25T00:25:11', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '38cf9c0c-081a-4430-bf0b-fb911724434b' User entered 'No (N)'	System	25 Dec 2020 08:25:23
	System	25 Dec 2020 08:25:23

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-25T00:25:15', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '38cf9c0c-081a-4430-bf0b-fb911724434b' User entered 'No (N)'	System	25 Dec 2020 08:25:23
	System	25 Dec 2020 08:25:23

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2020-12-25T00:25:18', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '38cf9c0c-081a-4430-bf0b-fb911724434b' User entered '25 Dec 2020 00:25:18'	System	25 Dec 2020 08:25:23
	System	25 Dec 2020 08:25:23

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-03T12:00:22', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '71f5e34c-8167-42d2-8927-28ae3d351dec'	System	03 Jan 2021 20:00:39
User entered 'No (N)'	System	03 Jan 2021 20:00:39

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-03T12:00:28', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '71f5e34c-8167-42d2-8927-28ae3d351dec'	System	03 Jan 2021 20:00:39
User entered 'No (N)'	System	03 Jan 2021 20:00:39

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-03T12:00:33', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '71f5e34c-8167-42d2-8927-28ae3d351dec' User entered '03 Jan 2021 12:00:33'	System	03 Jan 2021 20:00:39
	System	03 Jan 2021 20:00:39

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-15T04:12:26', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '6e321714-28ce-4d18-8f39-a0561e7f2b1a' User entered 'No (N)'	System	15 Jan 2021 12:12:34
	System	15 Jan 2021 12:12:34

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-15T04:12:29', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '6e321714-28ce-4d18-8f39-a0561e7f2b1a' User entered 'No (N)'	System	15 Jan 2021 12:12:34
	System	15 Jan 2021 12:12:34

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-15T04:12:32', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '6e321714-28ce-4d18-8f39-a0561e7f2b1a' User entered '15 Jan 2021 04:12:32'	System	15 Jan 2021 12:12:34
	System	15 Jan 2021 12:12:34

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-22T00:16:12', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd8945539-0f7f-45b4-b3fd-e9644808aae8'	System	22 Jan 2021 08:16:36
User entered 'No (N)'	System	22 Jan 2021 08:16:36



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-22T00:16:19', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd8945539-0f7f-45b4-b3fd-e9644808aae8'	System	22 Jan 2021 08:16:36
User entered 'No (N)'	System	22 Jan 2021 08:16:36

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-22T00:16:24', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd8945539-0f7f-45b4-b3fd-e9644808aae8' User entered '22 Jan 2021 00:16:24'	System	22 Jan 2021 08:16:36
	System	22 Jan 2021 08:16:36

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-29T04:15:10', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '84244164-4507-4da6-8d99-81b727255caf'	System	29 Jan 2021 12:15:21
User entered 'No (N)'	System	29 Jan 2021 12:15:21

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-29T04:15:14', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '84244164-4507-4da6-8d99-81b727255caf'	System	29 Jan 2021 12:15:21
User entered 'No (N)'	System	29 Jan 2021 12:15:21

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-01-29T04:15:17', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '84244164-4507-4da6-8d99-81b727255caf' User entered '29 Jan 2021 04:15:17'	System	29 Jan 2021 12:15:21



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-09T11:59:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2e1c6808-1142-4cf3-83a6-7475cb73f611' User entered 'No (N)'	System	09 Feb 2021 19:59:41
	System	09 Feb 2021 19:59:41

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-09T11:59:37', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2e1c6808-1142-4cf3-83a6-7475cb73f611' User entered 'No (N)'	System	09 Feb 2021 19:59:41

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-09T11:59:40', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2e1c6808-1142-4cf3-83a6-7475cb73f611' User entered '09 Feb 2021 11:59:40'	System	09 Feb 2021 19:59:41
	System	09 Feb 2021 19:59:41

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-14T13:08:33', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'b3831455-63aa-4cb0-97a8-610ae25a7087' User entered 'No (N)'	System	14 Feb 2021 21:08:41
	System	14 Feb 2021 21:08:41

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-14T13:08:35', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'b3831455-63aa-4cb0-97a8-610ae25a7087'	System	14 Feb 2021 21:08:41
User entered 'No (N)'	System	14 Feb 2021 21:08:41

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-14T13:08:38', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'b3831455-63aa-4cb0-97a8-610ae25a7087' User entered '14 Feb 2021 13:08:38'	System	14 Feb 2021 21:08:41
	System	14 Feb 2021 21:08:41

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-22T17:59:26', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'a1956261-7f51-4107-9b3b-1104c6d3b7af' User entered 'No (N)'	System	23 Feb 2021 01:59:36
	System	23 Feb 2021 01:59:36



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-22T17:59:28', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'a1956261-7f51-4107-9b3b-1104c6d3b7af' User entered 'No (N)'	System	23 Feb 2021 01:59:36
	System	23 Feb 2021 01:59:36

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-22T17:59:31', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'a1956261-7f51-4107-9b3b-1104c6d3b7af' User entered '22 Feb 2021 17:59:31'	System	23 Feb 2021 01:59:36
	System	23 Feb 2021 01:59:36

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-28T23:48:18-08:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2da9ba89-7cf4-49ee-b5a1-8db93fce80af'	System	01 Mar 2021 07:48:31
User entered 'No (N)'	System	01 Mar 2021 07:48:31

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-28T23:48:24-08:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2da9ba89-7cf4-49ee-b5a1-8db93fce80af'	System	01 Mar 2021 07:48:31
User entered 'No (N)'	System	01 Mar 2021 07:48:31

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-28T23:48:27-08:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '2da9ba89-7cf4-49ee-b5a1-8db93fce80af' User entered '28 Feb 2021 23:48:27'	System	01 Mar 2021 07:48:31
	System	01 Mar 2021 07:48:31



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-05T17:02:19-08:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '1ef1da41-b97f-41d0-9196-9206c2f07c68'	System	06 Mar 2021 01:02:58
User entered 'No (N)'	System	06 Mar 2021 01:02:58

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-05T17:02:22-08:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '1ef1da41-b97f-41d0-9196-9206c2f07c68'	System	06 Mar 2021 01:02:58
User entered 'No (N)'	System	06 Mar 2021 01:02:58

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-05T17:02:27-08:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '1ef1da41-b97f-41d0-9196-9206c2f07c68' User entered '05 Mar 2021 17:02:27'	System	06 Mar 2021 01:02:58
	System	06 Mar 2021 01:02:58

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-15T07:30:56-05:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f25abb89-c988-44a6-bf00-782296f3b44f'	System	15 Mar 2021 12:31:13
User entered 'No (N)'	System	15 Mar 2021 12:31:13

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-15T07:31:00-05:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f25abb89-c988-44a6-bf00-782296f3b44f'	System	15 Mar 2021 12:31:13
User entered 'No (N)'	System	15 Mar 2021 12:31:13

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-15T07:31:03-05:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f25abb89-c988-44a6-bf00-782296f3b44f' User entered '15 Mar 2021 07:31:03'	System	15 Mar 2021 12:31:13
	System	15 Mar 2021 12:31:13

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-22T22:57:15-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '56feb6da-2780-414c-a08f-3132b6e04ff2'	System	23 Mar 2021 05:57:25
User entered 'No (N)'	System	23 Mar 2021 05:57:25



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-22T22:57:19-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '56feb6da-2780-414c-a08f-3132b6e04ff2'	System	23 Mar 2021 05:57:25
User entered 'No (N)'	System	23 Mar 2021 05:57:25

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-22T22:57:21-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '56feb6da-2780-414c-a08f-3132b6e04ff2'	System	23 Mar 2021 05:57:25
User entered '22 Mar 2021 22:57:21'	System	23 Mar 2021 05:57:25

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-26T12:12:18-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'a1ec02eb-b1e9-4f24-9352-0be338c42990'	System	26 Mar 2021 19:12:27
User entered 'No (N)'	System	26 Mar 2021 19:12:27

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-26T12:12:22-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'a1ec02eb-b1e9-4f24-9352-0be338c42990' User entered 'No (N)'	System	26 Mar 2021 19:12:27
	System	26 Mar 2021 19:12:27

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-03-26T12:12:24-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'a1ec02eb-b1e9-4f24-9352-0be338c42990' User entered '26 Mar 2021 12:12:24'	System	26 Mar 2021 19:12:27
	System	26 Mar 2021 19:12:27



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-02T06:30:24-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5e4dbc2-ef9e-42c7-8894-22de4fd35ee1' User entered 'No (N)'	System	02 Apr 2021 13:30:33
	System	02 Apr 2021 13:30:33

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-02T06:30:27-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5e4dbc2-ef9e-42c7-8894-22de4fd35ee1'	System	02 Apr 2021 13:30:33
User entered 'No (N)'	System	02 Apr 2021 13:30:33

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-02T06:30:29-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd5e4dbc2-ef9e-42c7-8894-22de4fd35ee1' User entered '02 Apr 2021 06:30:29'	System	02 Apr 2021 13:30:33
	System	02 Apr 2021 13:30:33

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-10T23:13:34-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '823ae101-27d8-44f5-af60-06952273bc97'	System	11 Apr 2021 06:13:48
User entered 'No (N)'	System	11 Apr 2021 06:13:48

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-10T23:13:38-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '823ae101-27d8-44f5-af60-06952273bc97'	System	11 Apr 2021 06:13:48
User entered 'No (N)'	System	11 Apr 2021 06:13:48

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-10T23:13:41-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: '823ae101-27d8-44f5-af60-06952273bc97'	System	11 Apr 2021 06:13:48
User entered '10 Apr 2021 23:13:41'	System	11 Apr 2021 06:13:48

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-16T00:16:15-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c37c198d-5460-439c-b092-c4627bcd977'	System	16 Apr 2021 07:17:16
User entered 'No (N)'	System	16 Apr 2021 07:17:16



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-16T00:16:40-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c37c198d-5460-439c-b092-c4627bcd977'	System	16 Apr 2021 07:17:16
User entered 'No (N)'	System	16 Apr 2021 07:17:16

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-16T00:16:42-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'c37c198d-5460-439c-b092-c4627bcd977'	System	16 Apr 2021 07:17:16
User entered '16 Apr 2021 00:16:42'	System	16 Apr 2021 07:17:16

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-27T12:00:27-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'ba3c75da-aade-49b2-b787-880b6260fcee' User entered 'No (N)'	System	29 Apr 2021 06:38:04
	System	29 Apr 2021 06:38:04

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-27T12:00:29-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'ba3c75da-aade-49b2-b787-880b6260fcee' User entered 'No (N)'	System	29 Apr 2021 06:38:04
	System	29 Apr 2021 06:38:04

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-04-27T12:00:32-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'ba3c75da-aade-49b2-b787-880b6260fcee' User entered '27 Apr 2021 12:00:32'	System	29 Apr 2021 06:38:04
	System	29 Apr 2021 06:38:04



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-05-02T12:09:16-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd1ef4f98-f99e-4fe7-bf02-3bbfce5dec3f'	System	02 May 2021 19:09:58
User entered 'Yes (Y)'	System	02 May 2021 19:09:58

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

Have you been exposed to someone with 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 (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-05-02T12:09:23-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd1ef4f98-f99e-4fe7-bf02-3bbfce5dec3f'	System	02 May 2021 19:09:58
User entered 'No (N)'	System	02 May 2021 19:09:58

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-05-02T12:09:28-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd1ef4f98-f99e-4fe7-bf02-3bbfce5dec3f'	System	02 May 2021 19:09:58
User entered 'No (N)'	System	02 May 2021 19:09:58

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-05-02T12:09:34-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd1ef4f98-f99e-4fe7-bf02-3bbfce5dec3f' User entered 'Yes (Y)'	System	02 May 2021 19:09:58
	System	02 May 2021 19:09:58

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-05-02T12:09:43-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd1ef4f98-f99e-4fe7-bf02-3bbfce5dec3f'	System	02 May 2021 19:09:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 May 2021 19:09:58



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-05-02T12:09:48-07:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'd1ef4f98-f99e-4fe7-bf02-3bbfce5dec3f'	System	02 May 2021 19:09:58
User entered '02 May 2021 12:09:48'	System	02 May 2021 19:09:58

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:51:50



**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:51:50

**US3262259**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 21:51:50



**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:51:50



**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '04 Nov 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '08 Nov 2022 23:59'	System	19 Nov 2020 21:51:50



**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '11 Nov 2022 00:01'	System	19 Nov 2020 21:51:50

**US3262259**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:19:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:51:50
Amendment Manager: User entered '15 Nov 2022 23:59'	System	19 Nov 2020 21:51:50

US3262259

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:19:44**

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)	25 Apr 2021 03:17:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-28T23:48:10-08:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f391f038-81f6-4f01-a879-8766575d2fa3'	System	01 Mar 2021 07:48:15
User entered 'No (N)'	System	01 Mar 2021 07:48:15

**US3262259**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:17:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC606330-0BBF-4AF5-B2EA-DA98A577325B)', Time: '2021-02-28T23:48:13-08:00', User OID: 'PatientReportedOutcome (US3262259)', ODM File OID: 'f391f038-81f6-4f01-a879-8766575d2fa3' User entered '28 Feb 2021 23:48:13'	System	01 Mar 2021 07:48:15
	System	01 Mar 2021 07:48:15

**US3262259**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:57:57
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:34:29

**US3262259**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:57:57
User entered '02 Dec 2020'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:34:29

**US3262259**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:57:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:34:29



US3262259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:57:57
User entered empty.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:34:29
	(b) (4)	

US3262259

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:57:57
User entered 'Yes (Y)'	(b) (4) Daisy Langerica (b) (4)	26 Jan 2021 19:34:33

**US3262259**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:48:12
User entered 'I'	System	26 Jan 2021 19:34:33

**US3262259**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langerica (b) (4)	26 Jan 2021 19:35:04
	(b) (4)	

US3262259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 17:10:39
User entered '30 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:35:04

US3262259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 17:10:39
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:35:04

**US3262259**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 17:10:39
User entered empty.	Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:35:04

US3262259

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	26 Jan 2021 19:35:08
	(b) (4)	



**US3262259**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User entered 'I'	System	26 Jan 2021 19:35:08

US3262259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langerica (b) (4)	25 Feb 2021 22:56:03
	(b) (4)	

US3262259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:21:51
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'CORRECT AS IS PER SOURCE	Daisy Langarica (b) (4)	25 Feb 2021 22:58:55
' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	25 Feb 2021 22:56:03
User entered '26 Jan 2021'	Daisy Langarica (b) (4)	25 Feb 2021 22:56:03
	(b) (4)	

US3262259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 17:10:39
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4) (b) (4)	25 Feb 2021 22:56:03

US3262259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	25 Feb 2021 22:56:03
	(b) (4)	

US3262259

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	25 Feb 2021 22:58:26
	(b) (4)	

**US3262259**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User entered 'I'	System	25 Feb 2021 22:58:26

US3262259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	30 Mar 2021 18:42:26
	(b) (4)	
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4)	26 Mar 2021 15:14:23
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	26 Mar 2021 15:13:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 13:22:29
Query 'Data is required. Please complete.' answered with 'TRANSCRIPTION IN ERROR' (Site from System).	Daisy Langarica (b) (4)	25 Feb 2021 23:04:00
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 23:03:56
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4)	25 Feb 2021 23:03:56
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	25 Feb 2021 23:03:01
	(b) (4)	



US3262259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 07:52:11
User entered '08 Mar 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	30 Mar 2021 18:43:44
	(b) (4)	
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'incorrect ecrf' (Site from System).	Daisy Langarica (b) (4)	30 Mar 2021 18:43:36
	(b) (4)	
User entered '26 Feb 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	30 Mar 2021 18:42:55
	(b) (4)	
User entered '28 Feb 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	30 Mar 2021 18:42:44
	(b) (4)	
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Mar 2021 18:42:26
User entered '27 Feb 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	30 Mar 2021 18:42:26
	(b) (4)	
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Mar 2021 15:14:23
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	26 Mar 2021 15:14:23
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4)	26 Mar 2021 15:14:23
	(b) (4)	

US3262259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Feb 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	26 Mar 2021 15:13:58
User entered '26 Feb 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	26 Mar 2021 15:13:40
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Mar 2021 15:13:26
User entered '28 Feb 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	26 Mar 2021 15:13:26
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Feb 2021 23:03:56
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	25 Feb 2021 23:03:56
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4)	25 Feb 2021 23:03:56
User entered '06 Feb 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	25 Feb 2021 23:03:27
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Feb 2021 23:03:01
User entered '25 Feb 2021'	Daisy Langarica (b) (4)	25 Feb 2021 23:03:01

US3262259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4)	30 Mar 2021 18:42:26
reason for change: Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry	Daisy Langarica (b) (4)	26 Mar 2021 15:14:23
Error	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4)	26 Mar 2021 15:13:26
reason for change: Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry	Daisy Langarica (b) (4)	25 Feb 2021 23:03:56
Error	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4)	25 Feb 2021 23:03:01
	(b) (4)	

US3262259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	25 Feb 2021 23:03:01
	(b) (4)	

US3262259

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 20:42:59

**US3262259**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:03
User entered 'I'	System	26 Mar 2021 20:42:59

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	30 Mar 2021 18:29:50
	(b) (4)	

US3262259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:19:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '30 Mar 2021'	Daisy Langarica (b) (4)	30 Mar 2021 18:29:50
	(b) (4)	



US3262259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:19:44

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Clinic (Clinic)'	Daisy Langarica (b) (4)	30 Mar 2021 18:29:50
	(b) (4)	

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 18:29:50

US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	

US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '30 Mar 2021'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '10:00'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:00'	System	30 Mar 2021 18:30:33

US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '98.0' F	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	

US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Oral (Oral)'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	



US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	

US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '60'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 18:30:33

US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '12'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 18:30:33

US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '100'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:30:33

US3262259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '65'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:33
	(b) (4)	



**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:30:33

US3262259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:36
	(b) (4)	

US3262259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	30 Mar 2021 18:30:36
	(b) (4)	

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:44
	(b) (4)	

US3262259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '30 Mar 2021'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:44
	(b) (4)	

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '10:08'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:44
	(b) (4)	

**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:08'	System	30 Mar 2021 18:30:44

US3262259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	30 Mar 2021 18:30:47
	(b) (4)	



**US3262259**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 18:30:47

US3262259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4) System	13 Apr 2021 16:14:05
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	13 Apr 2021 16:14:05
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	09 Apr 2021 23:56:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 23:56:07
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 23:26:29
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 23:26:07

US3262259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	13 Apr 2021 16:14:05
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	13 Apr 2021 16:14:05
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4) (b) (4)	13 Apr 2021 16:14:05
User entered '08 Apr 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	13 Apr 2021 15:50:08
User entered '06 Apr 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	13 Apr 2021 15:49:56
User entered '11 Apr 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	13 Apr 2021 15:48:51
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Apr 2021 23:56:14
User entered '9 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	09 Apr 2021 23:56:14
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Apr 2021 23:26:29
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	08 Apr 2021 23:26:29
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 23:26:29

US3262259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Apr 2021 23:26:07
User entered '08 Apr 2021'	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 23:26:07

US3262259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4)	08 Apr 2021 23:26:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4)	08 Apr 2021 23:26:07
	(b) (4)	

**US3262259**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	08 Apr 2021 23:26:07
	(b) (4)	

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 18:47:18

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '26 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 18:47:18



**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 18:47:18

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 18:47:18

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:19:44

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '26 Jan 2021'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 18:47:34

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:19:44**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:51:29

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:19:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 18:47:34

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:19:44**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:51:29

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:19:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '26 Jan 2021'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 18:47:34

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:19:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Placebo (Placebo)'	(b) (4) Daisy Langerica (b) (4) (b) (4)	26 Jan 2021 18:47:34



US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:19:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Placebo (Placebo)'	(b) (4) Daisy Langerica (b) (4)	26 Jan 2021 18:47:34

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:19:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Placebo (Placebo)'	(b) (4) Daisy Langerica (b) (4)	26 Jan 2021 18:47:34

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:19:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 18:47:34

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:19:44**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered '1'	System	26 Jan 2021 18:47:34

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'I'	System	26 Jan 2021 18:47:34

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered empty.	System	26 Jan 2021 19:30:10
DataPoint set to visible.	System	26 Jan 2021 18:47:34



US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:19:44**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered empty.	System	26 Jan 2021 19:30:10
DataPoint set to visible.	System	26 Jan 2021 18:47:34

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '26 Jan 2021'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '10:32'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered '26 Jan 2021 10:32'	System	26 Jan 2021 19:30:10



US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '98.2' F	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered empty.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '65'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'bpm'	System	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '12'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'breaths/min'	System	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '116'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10



US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'mmHg'	System	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '76'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'mmHg'	System	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:19:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered empty.	System	26 Jan 2021 19:30:10
DataPoint set to visible.	System	26 Jan 2021 18:47:34

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10



US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '26 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '11:11'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered '26 Jan 2021 11:11'	System	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '98.6' F	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered empty.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '74'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'bpm'	System	26 Jan 2021 19:30:10



US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '18'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'breaths/min'	System	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '126'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'mmHg'	System	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '84'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'mmHg'	System	26 Jan 2021 19:30:10

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 18:48:08

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '26 Jan 2021'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 18:48:08



US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:27:28

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered empty.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:27:28

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered empty.	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:27:28

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'mRNA-1273'	System	26 Jan 2021 19:27:28
DataPoint set to visible.	System	26 Jan 2021 18:47:34

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '26 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:27:28

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '10:39'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 19:27:28

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:19:44**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered '26 Jan 2021 10:39'	System	26 Jan 2021 19:27:28

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 19:27:28



US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'ONCE'	System	26 Jan 2021 19:27:28

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 19:27:28

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 18:47:46

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '26 Jan 2021'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 18:47:46

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '10:37'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 18:47:46

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered '26 Jan 2021 10:37'	System	26 Jan 2021 18:47:46

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:19:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 18:47:58

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:19:44**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '26 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 18:47:58



**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:19:44**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '10:34'	(b) (4) Daisy Langarica (b) (4) (b) (4)	26 Jan 2021 18:47:58

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:19:44**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered '26 Jan 2021 10:34'	System	26 Jan 2021 18:47:58

US3262259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Jan 2021 18:48:01

**US3262259**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:41:14
User entered 'I'	System	26 Jan 2021 18:48:01

**US3262259**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:20
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:28:20

**US3262259**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:20
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '2 Feb 2021'	(b) (4), (b) (6)	02 Feb 2021 19:28:20

**US3262259**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:20
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Feb 2021 19:28:20

US3262259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:20
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:28:20



US3262259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:20
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:28:26

**US3262259**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:20
User entered 'I'	System	02 Feb 2021 19:28:26

**US3262259**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:20
User entered 'I'	System	02 Feb 2021 19:28:26
DataPoint set to visible.	System	02 Feb 2021 19:28:26

**US3262259**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:49:26

**US3262259**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '3 Mar 2021'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:49:26

US3262259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:19:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Clinic (Clinic)'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:49:26

**US3262259**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'OLD29'	System	05 Mar 2021 00:49:26

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User accepted default value 'Pre-Dose (PREDOSE)'	Atoya Adams (b) (4)	05 Mar 2021 00:51:23
	(b) (4)	



US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Atoya Adams (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '3 Mar 2021'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '09:09'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered '3 Mar 2021 09:09'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '98.0' F	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Oral (Oral)'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered empty.	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '65'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23



**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'bpm'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '17'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'breaths/min'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '127'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'mmHg'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '86'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'mmHg'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User accepted default value 'Post-Dose (POSTDOSE)'	Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23



US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '3 Mar 2021'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '09:53'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered '3 Mar 2021 09:53'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '98.5' F	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Oral (Oral)'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered empty.	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '68'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23



**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'bpm'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '16'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'breaths/min'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '123'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'mmHg'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '85'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:23

**US3262259**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'mmHg'	System	05 Mar 2021 00:51:23

US3262259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:37



US3262259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:19:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '3 Mar 2021'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:51:37

US3262259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:54:25

US3262259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered empty.	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:54:25

US3262259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

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)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered empty.	Atoya Adams (b) (4)	05 Mar 2021 00:54:25

US3262259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'mRNA-1273'	System	05 Mar 2021 00:54:25
DataPoint set to visible.	System	02 Feb 2021 19:28:26

US3262259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '3 Mar 2021'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:54:25

US3262259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered '09:18'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:54:25

**US3262259**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:19:44**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered '3 Mar 2021 09:18'	System	05 Mar 2021 00:54:25



US3262259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Atoya Adams (b) (4) (b) (4)	05 Mar 2021 00:54:25

US3262259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:19:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'ONCE'	System	05 Mar 2021 00:54:25

**US3262259**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:19:44**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 00:54:25

US3262259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) Atoya Adams (b) (4)	05 Mar 2021 00:54:30

US3262259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:35:36
User entered 'I'	System	05 Mar 2021 00:54:30

**US3262259**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:25:11
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:45:28

US3262259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:19:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:25:11
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:45:17
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 20:45:39
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Mar 2021 20:45:28
User entered '16 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 20:45:28

**US3262259**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:25:11
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:45:28



**US3262259**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:19:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:25:11
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:45:28

**US3262259**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:25:11
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:45:55

**US3262259**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:19:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:25:11
User entered 'I'	System	26 Mar 2021 20:45:55

**US3262259**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	30 Mar 2021 18:29:34
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '30 Mar 2021'	Daisy Langarica (b) (4)	30 Mar 2021 18:29:34
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Clinic (Clinic)'	Daisy Langarica (b) (4)	30 Mar 2021 18:29:34
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:19:44**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 18:29:34

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	



US3262259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '30 Mar 2021'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '10:00'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:00'	System	30 Mar 2021 18:31:24

US3262259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '98.0' F	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Oral (Oral)'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '60'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 18:31:24



US3262259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '12'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 18:31:24

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '100'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:31:24

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '65'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:24
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:19:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:31:24

**US3262259**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:19:44**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	30 Mar 2021 18:29:39
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:19:44**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	30 Mar 2021 18:29:39
	(b) (4)	



**US3262259**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:33
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '30 Mar 2021'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:33
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 17:10:39
	(b) (4)	
User entered '10:08'	Daisy Langarica (b) (4)	30 Mar 2021 18:31:33
	(b) (4)	

**US3262259**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:19:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:08'	System	30 Mar 2021 18:31:33

US3262259

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:19:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:34:21
User signature succeeded.	(b) (4)	
	Atoya Adams (b) (4)	03 May 2021 19:55:10
Signature has been broken.	(b) (4)	
	Daisy Langarica (b) (4)	03 May 2021 17:38:51
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	03 May 2021 17:38:51
	(b) (4)	
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:05:19
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	22 Oct 2020 15:09:37
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 18:18:50
User entered	System	03 May 2021 18:18:11
'USA-US069-2021-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	03 May 2021 18:18:11

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 May 2021 18:06:20
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	03 May 2021 18:06:20
Data point term sent to Coder	System	03 May 2021 17:41:08
User entered 'diarrhea of unknown etiology'	Daisy Langarica (b) (4) (b) (4)	03 May 2021 17:40:27

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	



US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered '01 May 2021'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 17:40:27

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	



**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 17:40:27

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still being worked up awaiting medical records ' (Site from System).	(b) (4)	
	Daisy Langarica (b) (4)	03 May 2021 17:41:09
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 May 2021 17:40:27
User entered 'I'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered '01 May 2021'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	



**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'None (NONE)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

None

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	03 May 2021 17:41:29
User entered '1' reason for change: Data Entry Error	Daisy Langarica (b) (4)	03 May 2021 17:41:29
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	03 May 2021 17:40:27
User entered '0'	Daisy Langarica (b) (4) (b) (4)	03 May 2021 17:40:27

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered 'Unknown (UNKNOWN)'	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

US3262259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:19:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	03 May 2021 17:40:27
	(b) (4)	

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 17:40:27

**US3262259**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 17:40:27



US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:19:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:27:28
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:37:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 15:15:13
User entered 'No (N)'	Alia Bober (b) (4)	22 Oct 2020 15:14:46
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Oct 2020 15:16:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:16:41
Data point term sent to Coder	System	22 Oct 2020 15:16:00
User entered 'Amodipine'	Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:16:00

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'Hypertension'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

US3262259

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered '10'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'once daily (QD)'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	



US3262259

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

US3262259

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'UN UNK 2012'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	

US3262259

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	22 Oct 2020 15:16:00
	(b) (4)	



**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 15:16:00

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 15:16:00

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 15:16:00

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: BENAZEPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Oct 2020 15:23:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:23:32
Data point term sent to Coder	System	22 Oct 2020 15:22:13
User entered 'Benazepril' reason for change: Data Entry Error	Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:21:20
Data point term sent to Coder	System	22 Oct 2020 15:18:07
User entered 'Benazapil'	Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:17:33

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'Hypertension'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered '10'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	



US3262259

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'once daily (QD)'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

US3262259

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

US3262259

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'UN UNK 2016'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	



**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	22 Oct 2020 15:17:33
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 15:17:33

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 15:17:33

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:19:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 15:17:33

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Oct 2020 15:20:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:20:36
Data point term sent to Coder	System	22 Oct 2020 15:19:09
User entered 'Hydrochlorothiazide'	Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:18:36

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'Hypertension'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	



**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered '6.25'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'once daily (QD)'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'UN UNK 2016'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	



**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	22 Oct 2020 15:18:36
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 15:18:36

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 15:18:36

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:19:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 15:18:36

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:49:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:49:37
Data point term sent to Coder	System	08 Apr 2021 23:38:26
Coding entries removed.	Daisy Langarica (b) (4)	08 Apr 2021 23:38:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 15:22:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 15:22:40
Data point term sent to Coder	System	22 Oct 2020 15:21:11
User entered 'Gabapentin'	Alia Bober (b) (4)	22 Oct 2020 15:20:28



US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered 'No (N)'	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User closed query 'Per DM CLR: Please specify the type of Neuropathy (e.g., Sensory or Motor). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:16:52
Query 'Per DM CLR: Please specify the type of Neuropathy (e.g., Sensory or Motor). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' answered with 'AS PER SUBJECTS CLARIFICATION - PINCHED NERVE ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 23:38:43
User entered 'PINCHED NERVE' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	08 Apr 2021 23:38:16
User opened query 'Per DM CLR: Please specify the type of Neuropathy (e.g., Sensory or Motor). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 07:51:51
User entered 'Left lower extremity neuropathy'	Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered '600'	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered 'mg (mg)'	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered empty.	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered 'three times daily (TID)'	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered empty.	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered 'Oral (ORAL)'	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28



US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered empty.	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered 'UN UNK 2019'	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered '0'	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 23:38:16
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	22 Oct 2020 15:20:28
	(b) (4)	

US3262259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered 'UN Mar 2021' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 23:38:16
User entered empty.	Daisy Langarica (b) (4)	22 Oct 2020 15:20:28
	(b) (4)	

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:17:10
User entered 'No (N)'	(b) (4) Alia Bober (b) (4) (b) (4)	22 Oct 2020 15:20:28

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User entered '3'	System	22 Oct 2020 15:20:28

**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User entered '1'	System	22 Oct 2020 15:20:28



**US3262259**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:19:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:58:33
User entered '804 (804)'	System	22 Oct 2020 15:20:28

US3262259

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 16:19:44**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:18:47
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	22 Oct 2020 15:15:04
	(b) (4)	

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:19:53
User entered 'USA-US069-2021-MRNA-1273-P301000007'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'Yes (Y)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'Yes (Y)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11



**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'Atoya'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'Adams'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered '2121 E. Flamingo Road'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'las vegas'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'NV'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered '89119'	System	03 May 2021 18:18:11



**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
User entered 'US'	(b) (4) System	03 May 2021 18:20:19

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:20:19

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:19:53
User entered 'USA-US069-2021-MRNA-1273-P301000007'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'Yes (Y)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'Yes (Y)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11



**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'No (N)'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'Atoya'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'Adams'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered '2121 E. Flamingo Road'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'las vegas'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered 'NV'	System	03 May 2021 18:18:11

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:04
User entered '89119'	System	03 May 2021 18:18:11



**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
User entered 'US'	(b) (4) System	03 May 2021 18:20:19

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:19:44**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:20:19

**US3262259**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:19:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
User entered '03/May/2021 14:20'	(b) (4) System	03 May 2021 18:20:19

US3262259

Folder: SAE USA-US069-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:19:44

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 May 2021 18:20:19