

US3262027 (Prod: AB Clinical Trials - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:15:03

All time stamps listed in this document are displayed in GMT



US3262027

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

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[Participant ID](#)

US3262027

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

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US3262027

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 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



US3262027

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
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) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input 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) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

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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) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

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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) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Condition	MUSCLE SPASMS
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Condition	ONCHYMOSIS OF TOES BILATERALLY
Start date (dd MMM yyyy)	UN APR 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)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

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



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	16:49 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 16:49
Height ( <i>xxx.x</i> )	62 in
Weight ( <i>xxx.x</i> )	152.2 lb
BMI ( <i>xxx.x</i> )	27.89595 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 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) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

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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**

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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) 12 Feb 2021 21:18:12

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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) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

What was the date of randomization? (dd MMM yyyy) 28 JUL 2020

What was the participant's randomization number? 184059

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Height	ND - Not Done
Weight	ND - Not Done



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	16:49 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 16:49
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	17:40 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 17:40
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

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) 28 JUL 2020

What was the treatment time? (00:00-23:59) 17:02 (24 HR)

Treatment Date and Time (derived) 28 JUL 2020 17:02

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JUL 2020
Collection time (00:00-23:59)	16:50 (24 HR)
Collection date and time (derived)	28 JUL 2020 16:50



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Collection date ( <i>dd MMM yyyy</i> )			28 JUL 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:45	28 JUL 2020 16:45
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

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 16:15:03

**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 97.2 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 28 JUL 2020 17:33

PC Open Date & Time 28 JUL 2020 17:22

PC Close Date & Time 28 JUL 2020 19:52



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °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	29 JUL 2020 08:16
PC Open Date & Time	28 JUL 2020 20:47
PC Close Date & Time	29 JUL 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 06:00

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 10:13

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**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

97.6 °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

01 AUG 2020 10:13

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**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

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 12:00

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**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

97.3 °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

03 AUG 2020 23:59

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**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

28 JUL 2020 17:35

PC Open Date & Time

28 JUL 2020 17:22

PC Close Date & Time

28 JUL 2020 19:52



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**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

29 JUL 2020 08:18

PC Open Date & Time

28 JUL 2020 20:47

PC Close Date & Time

29 JUL 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**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

30 JUL 2020 06:00

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**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

31 JUL 2020 10:14

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**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

01 AUG 2020 10:13

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**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

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**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

02 AUG 2020 12:01

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**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

04 AUG 2020 00:00

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**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 ☐



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 17:35
PC Open Date & Time	28 JUL 2020 17:22
PC Close Date & Time	28 JUL 2020 19:52



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**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 ☐



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 08:17
PC Open Date & Time	28 JUL 2020 20:47
PC Close Date & Time	29 JUL 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 06:01
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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 ☒



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 10:14
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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

51 of 2040

EAB) (1725)



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 10:14
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**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  
EAB) (1725)

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US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

Yes ☐

PC Time stamp

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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

55 of 2040

EAB) (1725)



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 12:01
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2040

EAB) (1725)



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 00:00
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59



US3262027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:19:26

Generated On: 09 Jun 2021 16:15:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:19:26

Generated On: 09 Jun 2021 16:15:03

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)	21 SEP 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:50
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:19:26

Generated On: 09 Jun 2021 16:15:03

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:41
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG



US3262027

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 10:11 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 10:11

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



US3262027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

09:55 (24 HR)

Collection date and time (derived)

21 SEP 2020 09:55



US3262027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:52	21 SEP 2020 09:52
Nasopharyngeal Swab 2	No		



US3262027

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 10:46

PC Open Date & Time

21 SEP 2020 10:31

PC Close Date & Time

21 SEP 2020 13:01



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 22 SEP 2020 10:12

PC Open Date & Time 21 SEP 2020 13:56

PC Close Date & Time 22 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 22 SEP 2020 12:07

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 19:59

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**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

97.9 °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

24 SEP 2020 22:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**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

97.6 °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

26 SEP 2020 00:58

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 06:09

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 02:57

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**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

21 SEP 2020 10:48

PC Open Date & Time

21 SEP 2020 10:31

PC Close Date & Time

21 SEP 2020 13:01



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**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

22 SEP 2020 10:15

PC Open Date & Time

21 SEP 2020 13:56

PC Close Date & Time

22 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**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

22 SEP 2020 12:08

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**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

23 SEP 2020 19:59

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**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

24 SEP 2020 22:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**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

26 SEP 2020 00:58

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**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

27 SEP 2020 06:10

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**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

28 SEP 2020 02:57

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**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 ☐



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 10:51
PC Open Date & Time	21 SEP 2020 10:31
PC Close Date & Time	21 SEP 2020 13:01



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**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 ☐



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 10:16
PC Open Date & Time	21 SEP 2020 13:56
PC Close Date & Time	22 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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 ☒



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:09
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

95 of 2040

EAB) (1725)



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 19:59
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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

97 of 2040

EAB) (1725)



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 22:50
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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

99 of 2040

EAB) (1725)



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 00:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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 ☒



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 06:10
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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 ☒



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 02:57
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59



US3262027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:18:12

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:19:26

Generated On: 09 Jun 2021 16:15:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:19:26

Generated On: 09 Jun 2021 16:15:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	08:35 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 08:35
Temperature ( <i>xxx.x</i> )	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	66 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3262027

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:19:26

Generated On: 09 Jun 2021 16:15:03

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.*



US3262027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:19:26

Generated On: 09 Jun 2021 16:15:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

08:40 (24 HR)

Collection date and time (derived)

19 OCT 2020 08:40



US3262027

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:19:26

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 SEP 2020 06:11:23
Patient Cloud Open Date & Time	27 SEP 2020 00:01
Patient Cloud Close Date & Time	01 OCT 2020 23:59



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

04 OCT 2020 04:07:45

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 OCT 2020 08:01:41

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 12:25:24

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 NOV 2020 01:31:47
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 00:05:58

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 00:55:40

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	19 NOV 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 NOV 2020 23:59
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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 12:00:42
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

03 DEC 2020 00:36:04

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

<b>TIMEPOINT</b>	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 <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	12 DEC 2020 12:01:01
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

20 DEC 2020 18:00:21

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

24 DEC 2020 00:02:03

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

02 JAN 2021 12:01:12

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 JAN 2021 19:12:31
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

14 JAN 2021 00:53:55

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

21 JAN 2021 04:18:12

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

28 JAN 2021 00:01:39

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

07 FEB 2021 17:59:54

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

11 FEB 2021 10:42:24

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 208

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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18 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

01 MAR 2021 08:05:11

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

04 MAR 2021 01:01:36

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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

11 MAR 2021 09:29:46

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 00:24:43
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 12:00:29

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

<b>TIMEPOINT</b>	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 00:45:51
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 12:01:20

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 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	18 APR 2021 18:00:01
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

<b>TIMEPOINT</b>	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 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	22 APR 2021 03:29:52
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 12:38:27

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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="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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUN 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 <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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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 ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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="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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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19 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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°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 ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	26 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59
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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 <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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	16 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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="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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 474

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 <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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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="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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 516

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 <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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	20 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JAN 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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 ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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 ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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 ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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 ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**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 ☐



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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="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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 MAR 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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="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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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="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"/>



**US3262027**

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

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**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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



**US3262027**

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

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**Generated On: 09 Jun 2021 16:15:03**

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

02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	07 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	28 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 AUG 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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="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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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15 AUG 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

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

15 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

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US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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"/>



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3262027

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:15:03

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		01 MAR 2021 08:05:34



US3262027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:31:14

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:31:14

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

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

Visit date (dd MMM yyyy)	08 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 MAR 2021
Time of assessment (00:00-23:59)	11:17 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 11:17
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3262027

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

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.*



US3262027

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 MAR 2021

Collection time (00:00-23:59)

11:25 (24 HR)

Collection date and time (derived)

08 MAR 2021 11:25



US3262027

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3262027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3262027

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:03:34

Generated On: 09 Jun 2021 16:15:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3262027**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

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*



**US3262027**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:15:03**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

Date of Contact	26 AUG 2020
Time of Contact	11:47
Date and Time of Contact (derived)	26 AUG 2020 11:47
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

Date of Visit	26 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	26 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 May 2021 19:54:40

Generated On: 09 Jun 2021 16:15:03

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---



US3262027

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	



US3262027

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:58
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3262027

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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



US3262027

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 AUG 2020



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

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

Visit date (dd MMM yyyy)

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

Folder OID	SICKD28
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US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

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.*



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 16:03:32

Generated On: 09 Jun 2021 16:15:03

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection



US3262027

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:03:33

Generated On: 09 Jun 2021 16:15:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE



US3262027

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 16:03:33

Generated On: 09 Jun 2021 16:15:03

Date of updated informed consent (dd MMM yyyy) 4 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 4 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_



US3262027

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 16:03:33

Generated On: 09 Jun 2021 16:15:03

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

Collection date (dd MMM yyyy)	4 FEB 2021
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Collection time (00:00-23:59)	9:01 (24 HR)
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Collection date and time (derived)	4 FEB 2021 9:01
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US3262027

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 16:03:33

Generated On: 09 Jun 2021 16:15:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 FEB 2021
Collection time (00:00 - 23:59)	8:59
Collection Date and Time (derived)	4 FEB 2021 8:59



US3262027

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Apr 2021 19:11:16

Generated On: 09 Jun 2021 16:15:03

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

AEID	USA-US069-2021-MRNA-1273-P30 1000006
Adverse event	PNEUMONIA
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)	08 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 APR 2021
Hospital Discharge Date (dd MMM yyyy)	11 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0



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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

AEID

Adverse event

INVESTIGATIONAL PRODUCT  
DELAY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

01 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

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 checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 19:53:27

Generated On: 09 Jun 2021 16:15:03

---

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

Yes ☒

No ☐

---

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

---



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication BACLOFEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE SPASMS

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) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
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) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication MORPHINE SULFATE-ER

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	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 2014
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)	2	
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) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication MORPHINE SULFATE - IR

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	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 2014	
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)	3	
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 (5)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication FLUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication LOWER EXTREMITY EDEMA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	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 APR 2020	
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 (6)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPORT

Dose per administration 10

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

If dose unit is Other, specify MULTIEQUIVALENTS

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 (6)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	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 APR 2020	
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 (7)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication TERBINAFININE

Prophylaxis Yes ☐  
No ☒

Indication ONYCHOMYCOSIS OF TOES

Dose per administration 250

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 (7)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	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 APR 2020	
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 (8)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 200

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 (8)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	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)		22 AUG 2020
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 checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE BODY ACHES

Dose per administration 200

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

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EAB) (1725)



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	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)	22 AUG 2020	
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 checked="" type="radio"/>
	No	<input 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"/>



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify Q 24 HRS

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 250

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

Q 24 HOURS

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

PRODUCTION RELEASE (v12.003

357 of 2040

EAB) (1725)



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 16:03:20

Generated On: 09 Jun 2021 16:15:03

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 16:03:19

Generated On: 09 Jun 2021 16:15:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 APR 2021	XR CHEST 1 VIEW FRONTAL - THE CARDIO MEDIASTINAL DEMONSTRATES NO ACUTE ABNORMALITIES LOW LUNG VOLUMES ARE PRESENT. RT UPPER AND LOWER LOBE INFILTRATES & OR ATELECTATIC CHANGES PRESENT NO EFFUSION OR	Adverse Event	
07 APR 2021	CULTURE BLOOD ARD - NO GROWTH AT FOUR DAYS VERIFIED - 12 APR 2021	Adverse Event	
07 APR 2021	SARS COV-2 LMC - NEGATIVE	Adverse Event	
07 APR 2021	CT ANGIO CHEST/W CONTRAST INC W/O IMAGES	Diagnostic	



US3262027

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:15:03

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 ☐



US3262027

Folder: SAE USA-US069-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 16:03:33

Generated On: 09 Jun 2021 16:15:03

SAEID	USA-US069-2021-MRNA-1273-P301000006
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



US3262027

Folder: SAE USA-US069-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 16:03:33

Generated On: 09 Jun 2021 16:15:03

SAEID	USA-US069-2021-MRNA-1273-P301000006
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)	20/APR/2021 14:28
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

US3262027 (Prod: AB Clinical Trials - Hunt - PPDS)



**US3262027**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:15:03**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'US3262027'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 23:54:05



US3262027

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:19:53
	(b) (4)	



US3262027

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '28 JUL 2020'	RWS_ENDPOINT	28 Jul 2020 23:54:06
	ENDPOINT (b) (4)	



US3262027

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Clinic (Clinic)'	Daisy Langarica (b) (4)	29 Jul 2020 00:19:53
	(b) (4)	



**US3262027**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'SCRN'	System	29 Jul 2020 00:19:53



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered (b) (6) 1947'	RWS_ENDPOINT	28 Jul 2020 23:54:07
	ENDPOINT (b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '72'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



**US3262027**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:15:03**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'YEARS'	System	29 Jul 2020 00:44:40



**US3262027**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:15:03**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '72'	System	29 Jul 2020 00:20:16



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Male (M)'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'I'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:15:03

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:44:40
	(b) (4)	



US3262027

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '28 Jul 2020'	Daisy Langarica (b) (4)	29 Jul 2020 00:20:16
	(b) (4)	



US3262027

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'Jul 2020'	System	29 Jul 2020 00:20:16



US3262027

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '2020'	System	29 Jul 2020 00:20:16



US3262027

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Amendment 1 (1)'	Daisy Langarica (b) (4)	29 Jul 2020 00:20:16
	(b) (4)	



US3262027

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:20:16
	(b) (4)	



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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:20:16
	(b) (4)	



US3262027

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:20:16
	(b) (4)	



US3262027

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	29 Jul 2020 00:20:16
	(b) (4)	



US3262027

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	RWS_ENDPOINT	28 Jul 2020 23:54:06
	ENDPOINT (b) (4)	



US3262027

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:15:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '1'	System	29 Jul 2020 00:20:20



US3262027

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:20:20
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:15:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:03
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
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)	21 Oct 2020 15:25:44
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 'There is no record of con med for congestive heart failure.' (Site from DM).	(b) (4)	28 Sep 2020 14:15:38
	(b) (4)	
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)	28 Sep 2020 09:41:33
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4)	29 Jul 2020 00:46:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Jul 2020 00:46:58
	(b) (4)	
Data point term sent to Coder	System	29 Jul 2020 00:46:09
User entered 'congestive heart failure'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:23
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'un Apr 2020'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:23
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:23
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:23
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:45:23
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:23
	(b) (4)	



**US3262027**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'Apr 2020'	System	29 Jul 2020 00:45:23



**US3262027**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '2020'	System	29 Jul 2020 00:45:23



US3262027

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:45:23



US3262027

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:45:23



US3262027

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 00:46:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 00:46:58
	(b) (4)	
Data point term sent to Coder	System	29 Jul 2020 00:46:09
User entered 'chronic back pain'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:44
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'un UNK 2014'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:44
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:44
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:44
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:45:44
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:45:44
	(b) (4)	



**US3262027**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'Jan 2014'	System	29 Jul 2020 00:45:44



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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '2014'	System	29 Jul 2020 00:45:44



US3262027

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:45:44



US3262027

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:45:44



US3262027

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
Query 'Per CDM: Response noted yet there is no concomitant medication listed for this condition. Please review and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:10:43
User opened query 'Per CDM: Response noted yet there is no concomitant medication listed for this condition. Please review and update as appropriate.' (Site from DM).		21 Oct 2020 15:28:29
User closed query 'Per DM CLR: Please specify the location of MUSCLE SPASMS. 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).		21 Oct 2020 15:28:29
Query 'Per DM CLR: Please specify the location of MUSCLE SPASMS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'The location of muscle spasms not recorded. Medical history updated. Con med listed for condition.' (Site from DM).	Alia Bober (b) (4)	28 Sep 2020 14:16:51
User opened query 'Per DM CLR: Please specify the location of MUSCLE SPASMS. 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)	28 Sep 2020 09:42:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\23.0.	Coder Import (b) (4)	29 Jul 2020 00:46:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Jul 2020 00:46:58
Data point term sent to Coder	System	29 Jul 2020 00:46:09



**US3262027**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Condition](#)

Audit	User	Time (GMT)
User entered 'muscle spasms'	Daisy Langarica (b) (4) (b) (4)	29 Jul 2020 00:46:01



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'un UNK 2014'	Daisy Langarica (b) (4)	29 Jul 2020 00:46:01
	(b) (4)	



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:46:01
	(b) (4)	



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:46:01
	(b) (4)	



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:46:01
	(b) (4)	



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:46:01
	(b) (4)	



**US3262027**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'Jan 2014'	System	29 Jul 2020 00:46:01



**US3262027**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '2014'	System	29 Jul 2020 00:46:01



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:46:01



US3262027

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:46:01



US3262027

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:15:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Onychomycosis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 20:38:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 20:38:31
	(b) (4)	
Data point term sent to Coder	System	29 Jul 2020 00:47:09
User entered 'onychomosis of toes bilaterally'	Daisy Langarica (b) (4)	29 Jul 2020 00:46:54
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'un Apr 2019'	Daisy Langarica (b) (4)	29 Jul 2020 00:46:54
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:15:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:46:54
	(b) (4)	



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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:15:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:46:54
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:46:54
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:15:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:46:54
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'Apr 2019'	System	29 Jul 2020 00:46:54



US3262027

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:15:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '2019'	System	29 Jul 2020 00:46:54



**US3262027**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:46:54



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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:46:54



US3262027

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 00:48:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 00:48:57
	(b) (4)	
Data point term sent to Coder	System	29 Jul 2020 00:48:12
User entered 'depression'	Daisy Langerica (b) (4)	29 Jul 2020 00:47:12
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'un UNK 2018'	Daisy Langarica (b) (4)	29 Jul 2020 00:47:12
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:47:12
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:47:12
	(b) (4)	



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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:47:12
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:47:12
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'Jan 2018'	System	29 Jul 2020 00:47:12



US3262027

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '2018'	System	29 Jul 2020 00:47:12



US3262027

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:47:12



US3262027

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:47:12



US3262027

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:15:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 10:38:02
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	29 Jul 2020 10:38:02
	(b) (4)	
Data point term sent to Coder	System	29 Jul 2020 00:48:12
User entered 'bilateral lower extremity edema'	Daisy Langarica (b) (4)	29 Jul 2020 00:47:34
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'un Apr 2020'	Daisy Langarica (b) (4)	29 Jul 2020 00:47:34
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:15:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:47:34
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:15:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:47:34
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:47:34
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:15:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:47:34
	(b) (4)	



US3262027

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'Apr 2020'	System	29 Jul 2020 00:47:34



**US3262027**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '2020'	System	29 Jul 2020 00:47:34



US3262027

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:47:34



US3262027

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered empty.	System	29 Jul 2020 00:47:34



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '28 Jul 2020'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '16:49'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered '28 Jul 2020 16:49'	System	29 Jul 2020 00:48:35



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '62' in	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	
DataPoint set to visible.	System	29 Jul 2020 00:20:20



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '152.2' lb	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	
DataPoint set to visible.	System	29 Jul 2020 00:20:20



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
Amendment Manager: User entered '27.89595'	System	16 Sep 2020 23:37:49
User entered '27.9'	System	29 Jul 2020 00:48:35
DataPoint set to visible.	System	29 Jul 2020 00:20:20



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'kg/m2'	System	29 Jul 2020 00:48:35
DataPoint set to visible.	System	29 Jul 2020 00:20:20



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query 'Per CDM RQ: Previous query response noted.As per CCG "If Participant is screened and dosed on the same day then 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please refer to eCRF specific instructions and consider updating "ND" in the data fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 20:23:54
Query 'Per CDM RQ: Previous query response noted.As per CCG "If Participant is screened and dosed on the same day then 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please refer to eCRF specific instructions and consider updating "ND" in the data fields as appropriate. ' answered with 'UPDATED' (Site from DM).	Daisy Langarica (b) (4)	29 Oct 2020 18:38:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Oct 2020 18:38:36
User opened query 'Per CDM RQ: Previous query response noted.As per CCG "If Participant is screened and dosed on the same day then 'ND' should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please refer to eCRF specific instructions and consider updating "ND" in the data fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:24:15
User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:17:10
Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4)	20 Oct 2020 16:02:02
User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:26:59



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:26:59
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	26 Sep 2020 16:13:17
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:47:14
User entered '97.9' F	Daisy Langarica (b) (4) (b) (4)	29 Jul 2020 00:48:35



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User closed query 'Per CDM: Please remove data as this field should be blank.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 20:23:53
User entered empty; reason for change Data Entry Error	Daisy Langarica (b) (4)	29 Oct 2020 18:38:36
	(b) (4)	
Query 'Per CDM: Please remove data as this field should be blank.' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4)	20 Oct 2020 16:02:07
	(b) (4)	
User opened query 'Per CDM: Please remove data as this field should be blank.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:28:10
User entered 'Oral (Oral)'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	29 Oct 2020 18:38:36
	(b) (4)	
User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:20:12
Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4)	20 Oct 2020 16:02:12
	(b) (4)	
User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:27:06
User entered '81'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	



**US3262027**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'bpm'	System	29 Jul 2020 00:48:35



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
	(b) (4)	
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	29 Oct 2020 18:38:36
	(b) (4)	
User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:20:22
	(b) (4)	
Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4)	20 Oct 2020 16:02:18
	(b) (4)	
User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:27:11
	(b) (4)	
User entered '16'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'breaths/min'	System	29 Jul 2020 00:48:35



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	29 Oct 2020 18:38:36
	(b) (4)	
User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:22:40
Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4)	20 Oct 2020 16:02:23
	(b) (4)	
User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:27:17
User entered '114'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'mmHg'	System	29 Jul 2020 00:48:35



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
	(b) (4)	
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Daisy Langarica (b) (4)	29 Oct 2020 18:38:36
	(b) (4)	
User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:22:49
	(b) (4)	
Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4)	20 Oct 2020 16:02:28
	(b) (4)	
User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:27:22
	(b) (4)	
User entered '69'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:35
	(b) (4)	



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User entered 'mmHg'	System	29 Jul 2020 00:48:35



**US3262027**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44



US3262027

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44



US3262027

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:50
	(b) (4)	



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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '28 Jul 2020'	Daisy Langarica (b) (4)	29 Jul 2020 00:48:50
	(b) (4)	



US3262027

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:03

**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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:03

**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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



US3262027

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:03

**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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langerica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



US3262027

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:03

**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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langerica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



US3262027

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:03

[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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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[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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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**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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langerica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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**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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langerica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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[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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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**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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langerica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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**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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langerica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered 'I'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langerica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langerica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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Form: Risk of Exposure

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**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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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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 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langerica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:15:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:50:11
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:20:33



**US3262027**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '28 Jul 2020'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:20:33



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[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 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:20:33
	(b) (4)	



**US3262027**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'VISIT1'	System	29 Jul 2020 00:20:33



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 23:59:11



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:03

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:11:44
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:11:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 23:59:11
User entered '184059' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 23:59:11



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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 23:59:11



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Folder: Visit 1 Day 1

Form: Randomization

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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 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	02 Aug 2020 22:07:06



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Folder: Visit 1 Day 1

Form: Randomization

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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 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	02 Aug 2020 22:07:06



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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'No (N)'	(b) (4) Daisy Langerica (b) (4)	02 Aug 2020 22:07:06



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Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	02 Aug 2020 22:07:06



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:15:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	02 Aug 2020 22:07:06
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 09:34:32
Query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	26 Sep 2020 16:13:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	26 Sep 2020 16:13:39
User opened query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 14:23:13
User entered '62' in	Daisy Langerica (b) (4) (b) (4)	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 16:13:39
User entered '152.2' lb	Alia Bober (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 09:34:32
Query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	26 Sep 2020 16:13:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	26 Sep 2020 16:13:39
User opened query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 14:23:13
User entered '62' in	Daisy Langarica (b) (4) (b) (4)	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 16:13:39
User entered '152.2' lb	Alia Bober (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query 'Per CDM: As per CCG, If screened and dosed on the same day, Pre-dose page must be filled completely. Please review and update accordingly' (Site from DM).	(b) (4)	
Query 'Per CDM: As per CCG, If screened and dosed on the same day, Pre-dose page must be filled completely. Please review and update accordingly' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:53:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Alia Bober (b) (4)	20 Oct 2020 16:05:04
User opened query 'Per CDM: As per CCG, If screened and dosed on the same day, Pre-dose page must be filled completely. Please review and update accordingly' (Site from DM).	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 12:05:54
	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '28 Jul 2020' reason for change: Data Entry Error	(b) (4)	
	Alia Bober (b) (4)	20 Oct 2020 16:04:50
User entered empty.	(b) (4)	
	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '16:49' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 16:04:50
User entered empty.	Alia Bober (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '28 Jul 2020 16:49'	System	20 Oct 2020 16:04:50
User entered empty.	System	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '97.9' F reason for change: Data Entry Error	(b) (4)	20 Oct 2020 16:04:50
User entered empty.	Alia Bober (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Oct 2020 16:05:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	20 Oct 2020 16:05:10
User entered 'Oral (Oral)' reason for change: Data Entry Error	Alia Bober (b) (4)	20 Oct 2020 16:05:10
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Oct 2020 16:04:50
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4) (b) (4)	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '81' reason for change: Data Entry Error	(b) (4)	
	Alia Bober (b) (4)	20 Oct 2020 16:04:50
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'bpm'	System	20 Oct 2020 16:04:50
User entered empty.	System	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Alia Bober (b) (4)	20 Oct 2020 16:04:50
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'breaths/min'	System	20 Oct 2020 16:04:50
User entered empty.	System	29 Jul 2020 00:53:23



US3262027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '114' reason for change: Data Entry Error	(b) (4) Alia Bober (b) (4)	20 Oct 2020 16:04:50
User entered empty.	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	20 Oct 2020 16:04:50
User entered empty.	System	29 Jul 2020 00:53:23



US3262027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '69' reason for change: Data Entry Error	(b) (4)	
	Alia Bober (b) (4)	20 Oct 2020 16:04:50
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	20 Oct 2020 16:04:50
User entered empty.	System	29 Jul 2020 00:53:23



US3262027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 09:34:32
Query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	26 Sep 2020 16:13:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	26 Sep 2020 16:13:39
User opened query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 14:23:13
User entered '62' in	Daisy Langerica (b) (4) (b) (4)	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:15:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Sep 2020 16:13:39
User entered '152.2' lb	Alia Bober (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4) (b) (4)	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '28 Jul 2020'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'CORRECT AS IS ' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 17:44:36
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	Daisy Langarica (b) (4)	29 Jul 2020 00:54:08
User entered '17:40'	(b) (4)	
	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '28 Jul 2020 17:40'	System	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '97.2' F	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4) (b) (4)	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Jul 2020 00:53:58
Query 'Data is required. Please provide.' answered by System	System	29 Jul 2020 00:53:58
data change (Site from System).		29 Jul 2020 00:53:58
User entered '85' reason for change: Data Entry	Daisy Langarica (b) (4)	29 Jul 2020 00:53:58
Error	(b) (4)	29 Jul 2020 00:53:23
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 00:53:23
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'bpm'	System	29 Jul 2020 00:53:58
User entered empty.	System	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Jul 2020 00:53:58
Query 'Data is required. Please provide.' answered by System	System	29 Jul 2020 00:53:58
data change (Site from System).		29 Jul 2020 00:53:58
User entered '14' reason for change: Data Entry	Daisy Langarica (b) (4)	29 Jul 2020 00:53:58
Error	(b) (4)	29 Jul 2020 00:53:23
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 00:53:23
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'breaths/min'	System	29 Jul 2020 00:53:58
User entered empty.	System	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Jul 2020 00:53:58
Query 'Data is required. Please provide.' answered by System	System	29 Jul 2020 00:53:58
data change (Site from System).		29 Jul 2020 00:53:58
User entered '122' reason for change: Data Entry	Daisy Langarica (b) (4)	29 Jul 2020 00:53:58
Error	(b) (4)	29 Jul 2020 00:53:23
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 00:53:23
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	29 Jul 2020 00:53:58
User entered empty.	System	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Jul 2020 00:53:58
Query 'Data is required. Please provide.' answered by System	System	29 Jul 2020 00:53:58
data change (Site from System).		29 Jul 2020 00:53:58
User entered '72' reason for change: Data Entry	Daisy Langarica (b) (4)	29 Jul 2020 00:53:58
Error	(b) (4)	29 Jul 2020 00:53:23
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Jul 2020 00:53:23
User entered empty.	Daisy Langarica (b) (4)	29 Jul 2020 00:53:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	29 Jul 2020 00:53:58
User entered empty.	System	29 Jul 2020 00:53:23



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:21:41



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:21:41



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:20:56



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:20:56
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

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 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:20:56
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 00:20:56



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '28 Jul 2020'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:20:56



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '17:02'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:20:56
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '28 Jul 2020 17:02'	System	29 Jul 2020 00:20:56



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:20:56
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'ONCE'	System	29 Jul 2020 00:20:56



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 00:20:56



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	02 Aug 2020 22:06:54



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '28 Jul 2020'	(b) (4) Daisy Langarica (b) (4) (b) (4)	02 Aug 2020 22:06:54



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '16:50'	(b) (4) Daisy Langarica (b) (4) (b) (4)	02 Aug 2020 22:06:54



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '28 Jul 2020 16:50'	System	02 Aug 2020 22:06:54



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:15:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '28 Jul 2020'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:21:34
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Daisy Langarica (b) (4)	29 Jul 2020 00:21:34



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:21:34



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '16:45'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:21:34
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '28 Jul 2020 16:45'	System	29 Jul 2020 00:21:34



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Daisy Langarica (b) (4)	29 Jul 2020 00:21:34



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:21:34
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	29 Jul 2020 00:21:34



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered empty.	System	29 Jul 2020 00:21:34



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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langerica (b) (4)	29 Jul 2020 00:21:04



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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '1'	System	29 Jul 2020 00:21:04



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:33:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '41a166b6-6137-4e5e-a5ce-ae0192cc1261' User entered 'Yes (Y)'	System	29 Jul 2020 00:33:58
	System	29 Jul 2020 00:33:58



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAF)', Time: '2020-07-28T17:33:29', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '41a166b6-6137-4e5e-a5ce-ae0192cc1261' User entered '97.2'	System	29 Jul 2020 00:33:58
	System	29 Jul 2020 00:33:58



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:33:36', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '41a166b6-6137-4e5e-a5ce-ae0192cc1261'	System	29 Jul 2020 00:33:58
User entered 'Yes (Y)'	System	29 Jul 2020 00:33:58



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'nothing was taken in clinic this was a typo ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 10:41:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:33:41', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '41a166b6-6137-4e5e-a5ce-ae0192cc1261' User entered '1'	Daisy Langarica (b) (4) (b) (4)	23 Nov 2020 18:23:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	29 Jul 2020 00:33:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:33:41', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '41a166b6-6137-4e5e-a5ce-ae0192cc1261' User entered '1'	System	29 Jul 2020 00:33:58
User entered '1'	System	29 Jul 2020 00:33:58



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAF)', Time: '2020-07-28T17:33:41', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '41a166b6-6137-4e5e-a5ce-ae0192cc1261' User entered '0'	System	29 Jul 2020 00:33:58
	System	29 Jul 2020 00:33:58



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:33:55', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '41a166b6-6137-4e5e-a5ce-ae0192cc1261' User entered '28 Jul 2020 17:33'	System	29 Jul 2020 00:33:58
	System	29 Jul 2020 00:33:58



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Jul 2020 17:22'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Jul 2020 19:52'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:15:46', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '554ee93a-05fd-46da-ad51-a62ee4f899cf' User entered 'Yes (Y)'	System	29 Jul 2020 15:16:23
	System	29 Jul 2020 15:16:23



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:15:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '554ee93a-05fd-46da-ad51-a62ee4f899cf' User entered '97.3'	System	29 Jul 2020 15:16:23
	System	29 Jul 2020 15:16:23



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:16:01', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '554ee93a-05fd-46da-ad51-a62ee4f899cf' User entered 'No (N)'	System	29 Jul 2020 15:16:23
	System	29 Jul 2020 15:16:23



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:16:13', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '554ee93a-05fd-46da-ad51-a62ee4f899cf' User entered '29 Jul 2020 08:16'	System	29 Jul 2020 15:16:23
	System	29 Jul 2020 15:16:23



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Jul 2020 20:47'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '29 Jul 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 2'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T05:59:41', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'e93502e3-b641-4dc7-b2a4-4b28ded1985c' User entered 'Yes (Y)'	System	30 Jul 2020 13:00:16
	System	30 Jul 2020 13:00:16



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:00:02', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'e93502e3-b641-4dc7-b2a4-4b28ded1985c' User entered '97.6'	System	30 Jul 2020 13:00:16
	System	30 Jul 2020 13:00:16



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-30T06:00:06', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'e93502e3-b641-4dc7-b2a4-4b28ded1985c'	System	30 Jul 2020 13:00:16
User entered 'No (N)'	System	30 Jul 2020 13:00:16



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:00:14', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'e93502e3-b641-4dc7-b2a4-4b28ded1985c' User entered '30 Jul 2020 06:00'	System	30 Jul 2020 13:00:16
	System	30 Jul 2020 13:00:16



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '29 Jul 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 3'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:13:23', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '3a0725f5-6dc4-41bb-939b-b5cc22e4d448'	System	31 Jul 2020 17:13:51
User entered 'Yes (Y)'	System	31 Jul 2020 17:13:51



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:13:37', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '3a0725f5-6dc4-41bb-939b-b5cc22e4d448' User entered '97.8'	System	31 Jul 2020 17:13:51
	System	31 Jul 2020 17:13:51



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:13:42', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '3a0725f5-6dc4-41bb-939b-b5cc22e4d448'	System	31 Jul 2020 17:13:51
User entered 'No (N)'	System	31 Jul 2020 17:13:51



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-07-31T10:13:48', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '3a0725f5-6dc4-41bb-939b-b5cc22e4d448'	System	31 Jul 2020 17:13:51
User entered '31 Jul 2020 10:13'	System	31 Jul 2020 17:13:51



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 4'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:12:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0f381812-a3f1-4ea0-b633-514ae7223bd4' User entered 'Yes (Y)'	System	01 Aug 2020 17:13:17
	System	01 Aug 2020 17:13:17



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:04', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0f381812-a3f1-4ea0-b633-514ae7223bd4' User entered '97.6'	System	01 Aug 2020 17:13:17
	System	01 Aug 2020 17:13:17



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:08', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0f381812-a3f1-4ea0-b633-514ae7223bd4'	System	01 Aug 2020 17:13:17
User entered 'No (N)'	System	01 Aug 2020 17:13:17



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:14', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0f381812-a3f1-4ea0-b633-514ae7223bd4' User entered '01 Aug 2020 10:13'	System	01 Aug 2020 17:13:17
	System	01 Aug 2020 17:13:17



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 5'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 6'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:00:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2b13d7a7-b2cc-470f-8071-90ddbe5b872e' User entered 'Yes (Y)'	System	02 Aug 2020 19:00:47
	System	02 Aug 2020 19:00:47



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:00:35', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2b13d7a7-b2cc-470f-8071-90ddbe5b872e' User entered '97.8'	System	02 Aug 2020 19:00:47
	System	02 Aug 2020 19:00:47



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-08-02T12:00:38', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2b13d7a7-b2cc-470f-8071-90ddbe5b872e'	System	02 Aug 2020 19:00:47
User entered 'No (N)'	System	02 Aug 2020 19:00:47



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:00:43', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2b13d7a7-b2cc-470f-8071-90ddbe5b872e' User entered '02 Aug 2020 12:00'	System	02 Aug 2020 19:00:47
	System	02 Aug 2020 19:00:47



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 7'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-03T23:59:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '536a065e-ebd7-4b80-8b2d-dda07c54d070'	System	04 Aug 2020 06:59:43
User entered 'Yes (Y)'	System	04 Aug 2020 06:59:43



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-03T23:59:32', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '536a065e-ebd7-4b80-8b2d-dda07c54d070' User entered '97.3'	System	04 Aug 2020 06:59:43
	System	04 Aug 2020 06:59:43



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-03T23:59:36', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '536a065e-ebd7-4b80-8b2d-dda07c54d070'	System	04 Aug 2020 06:59:43
User entered 'No (N)'	System	04 Aug 2020 06:59:43



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-03T23:59:41', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '536a065e-ebd7-4b80-8b2d-dda07c54d070' User entered '03 Aug 2020 23:59'	System	04 Aug 2020 06:59:43
	System	04 Aug 2020 06:59:43



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-28T17:35:38', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f9fee473-8db8-4e90-93f6-bf9c3b4042b2'	System	29 Jul 2020 00:36:01
User entered 'None (1)'	System	29 Jul 2020 00:36:01



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:35:42', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f9fee473-8db8-4e90-93f6-bf9c3b4042b2'	System	29 Jul 2020 00:36:01
User entered 'No (N)'	System	29 Jul 2020 00:36:01



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:35:46', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f9fee473-8db8-4e90-93f6-bf9c3b4042b2'	System	29 Jul 2020 00:36:01
User entered 'No (N)'	System	29 Jul 2020 00:36:01



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-28T17:35:50', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f9fee473-8db8-4e90-93f6-bf9c3b4042b2'	System	29 Jul 2020 00:36:01
User entered 'None (1)'	System	29 Jul 2020 00:36:01



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:35:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f9fee473-8db8-4e90-93f6-bf9c3b4042b2'	System	29 Jul 2020 00:36:01
User entered '28 Jul 2020 17:35'	System	29 Jul 2020 00:36:01



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Jul 2020 17:22'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Jul 2020 19:52'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-29T08:17:50', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '832a3913-4722-4a24-b296-9fce0206d12e'	System	29 Jul 2020 15:18:19
User entered 'None (1)'	System	29 Jul 2020 15:18:19



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-29T08:17:53', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '832a3913-4722-4a24-b296-9fce0206d12e' User entered 'No (N)'	System	29 Jul 2020 15:18:19
	System	29 Jul 2020 15:18:19



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-29T08:17:58', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '832a3913-4722-4a24-b296-9fce0206d12e' User entered 'No (N)'	System	29 Jul 2020 15:18:19
	System	29 Jul 2020 15:18:19



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-29T08:18:11', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '832a3913-4722-4a24-b296-9fce0206d12e'	System	29 Jul 2020 15:18:19
User entered 'None (1)'	System	29 Jul 2020 15:18:19



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:18:18', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '832a3913-4722-4a24-b296-9fce0206d12e' User entered '29 Jul 2020 08:18'	System	29 Jul 2020 15:18:19
	System	29 Jul 2020 15:18:19



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Jul 2020 20:47'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '29 Jul 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 2'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-30T06:00:24', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5321b3cc-7068-4d2e-aa96-dbc51496f297'	System	30 Jul 2020 13:00:45
User entered 'None (1)'	System	30 Jul 2020 13:00:45



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:00:28', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5321b3cc-7068-4d2e-aa96-dbc51496f297'	System	30 Jul 2020 13:00:45
User entered 'No (N)'	System	30 Jul 2020 13:00:45



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-30T06:00:32', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5321b3cc-7068-4d2e-aa96-dbc51496f297'	System	30 Jul 2020 13:00:45
User entered 'No (N)'	System	30 Jul 2020 13:00:45



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-30T06:00:36', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5321b3cc-7068-4d2e-aa96-dbc51496f297'	System	30 Jul 2020 13:00:45
User entered 'None (1)'	System	30 Jul 2020 13:00:45



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:00:42', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5321b3cc-7068-4d2e-aa96-dbc51496f297' User entered '30 Jul 2020 06:00'	System	30 Jul 2020 13:00:45
	System	30 Jul 2020 13:00:45



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '29 Jul 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 3'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAF)', Time: '2020-07-31T10:13:58', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c60a89b2-fb73-43c8-b52b-ccc8d274ecd9'	System	31 Jul 2020 17:14:26
User entered 'None (1)'	System	31 Jul 2020 17:14:26



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:03', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c60a89b2-fb73-43c8-b52b-ccc8d274ecd9' User entered 'No (N)'	System	31 Jul 2020 17:14:26
	System	31 Jul 2020 17:14:26



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:06', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c60a89b2-fb73-43c8-b52b-ccc8d274ecd9' User entered 'No (N)'	System	31 Jul 2020 17:14:26
	System	31 Jul 2020 17:14:26



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-07-31T10:14:17', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c60a89b2-fb73-43c8-b52b-ccc8d274ecd9'	System	31 Jul 2020 17:14:26
User entered 'None (1)'	System	31 Jul 2020 17:14:26



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-07-31T10:14:23', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c60a89b2-fb73-43c8-b52b-ccc8d274ecd9'	System	31 Jul 2020 17:14:26
User entered '31 Jul 2020 10:14'	System	31 Jul 2020 17:14:26



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 4'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAF)', Time: '2020-08-01T10:13:18', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a5ae33ac-61ad-4e50-9d21-b40f1483d9d5'	System	01 Aug 2020 17:13:37
User entered 'None (1)'	System	01 Aug 2020 17:13:37



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:21', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a5ae33ac-61ad-4e50-9d21-b40f1483d9d5'	System	01 Aug 2020 17:13:37
User entered 'No (N)'	System	01 Aug 2020 17:13:37



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:27', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a5ae33ac-61ad-4e50-9d21-b40f1483d9d5'	System	01 Aug 2020 17:13:37
User entered 'No (N)'	System	01 Aug 2020 17:13:37



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-08-01T10:13:30', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a5ae33ac-61ad-4e50-9d21-b40f1483d9d5'	System	01 Aug 2020 17:13:37
User entered 'None (1)'	System	01 Aug 2020 17:13:37



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:34', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a5ae33ac-61ad-4e50-9d21-b40f1483d9d5'	System	01 Aug 2020 17:13:37
User entered '01 Aug 2020 10:13'	System	01 Aug 2020 17:13:37



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 5'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



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Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 6'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-08-02T12:00:54', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19074e00-fd6b-4914-aef7-9030e6a9a86a'	System	02 Aug 2020 19:01:12
User entered 'None (1)'	System	02 Aug 2020 19:01:12



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:00:57', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19074e00-fd6b-4914-aef7-9030e6a9a86a' User entered 'No (N)'	System	02 Aug 2020 19:01:12
	System	02 Aug 2020 19:01:12



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-08-02T12:01:02', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19074e00-fd6b-4914-aef7-9030e6a9a86a' User entered 'No (N)'	System	02 Aug 2020 19:01:12
	System	02 Aug 2020 19:01:12



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:06', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19074e00-fd6b-4914-aef7-9030e6a9a86a' User entered 'None (1)'	System	02 Aug 2020 19:01:12
	System	02 Aug 2020 19:01:12



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:10', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19074e00-fd6b-4914-aef7-9030e6a9a86a' User entered '02 Aug 2020 12:01'	System	02 Aug 2020 19:01:12
	System	02 Aug 2020 19:01:12



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 7'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-03T23:59:48', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '645f1770-91e0-4e3e-b40f-92bde32fca5c'	System	04 Aug 2020 07:00:09
User entered 'None (1)'	System	04 Aug 2020 07:00:09



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-03T23:59:52', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '645f1770-91e0-4e3e-b40f-92bde32fca5c'	System	04 Aug 2020 07:00:09
User entered 'No (N)'	System	04 Aug 2020 07:00:09



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-08-03T23:59:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '645f1770-91e0-4e3e-b40f-92bde32fca5c'	System	04 Aug 2020 07:00:09
User entered 'No (N)'	System	04 Aug 2020 07:00:09



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-08-04T00:00:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '645f1770-91e0-4e3e-b40f-92bde32fca5c'	System	04 Aug 2020 07:00:09
User entered 'None (1)'	System	04 Aug 2020 07:00:09



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-04T00:00:06', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '645f1770-91e0-4e3e-b40f-92bde32fca5c' User entered '04 Aug 2020 00:00'	System	04 Aug 2020 07:00:09
	System	04 Aug 2020 07:00:09



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:34:26', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'dfda8e71-2f5c-412a-a710-9df4ac45f653'	System	29 Jul 2020 00:35:32
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		29 Jul 2020 00:35:32



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:34:49', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'dfda8e71-2f5c-412a-a710-9df4ac45f653'	System	29 Jul 2020 00:35:32
User entered 'None (0)'	System	29 Jul 2020 00:35:32



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:34:55', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'dfda8e71-2f5c-412a-a710-9df4ac45f653'	System	29 Jul 2020 00:35:32
User entered 'None (0)'	System	29 Jul 2020 00:35:32



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:35:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'dfda8e71-2f5c-412a-a710-9df4ac45f653' User entered 'None (0)'	System	29 Jul 2020 00:35:32
	System	29 Jul 2020 00:35:32



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:35:03', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'dfda8e71-2f5c-412a-a710-9df4ac45f653'	System	29 Jul 2020 00:35:32
User entered 'None (0)'	System	29 Jul 2020 00:35:32



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:35:06', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'dfda8e71-2f5c-412a-a710-9df4ac45f653'	System	29 Jul 2020 00:35:32
User entered 'None (0)'	System	29 Jul 2020 00:35:32



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:35:15', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'dfda8e71-2f5c-412a-a710-9df4ac45f653'	System	29 Jul 2020 00:35:32
User entered 'No (N)'	System	29 Jul 2020 00:35:32



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-28T17:35:29', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'dfda8e71-2f5c-412a-a710-9df4ac45f653'	System	29 Jul 2020 00:35:32
User entered '28 Jul 2020 17:35'	System	29 Jul 2020 00:35:32



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Jul 2020 17:22'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Jul 2020 19:52'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:16:37', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '86f4dee4-cac9-4a4f-bbfe-b9d6a2762dd2' User entered 'None (0)'	System	29 Jul 2020 15:17:42
	System	29 Jul 2020 15:17:42



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:16:45', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '86f4dee4-cac9-4a4f-bbfe-b9d6a2762dd2'	System	29 Jul 2020 15:17:42
User entered 'No interference with activity (1)'	System	29 Jul 2020 15:17:42



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:16:50', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '86f4dee4-cac9-4a4f-bbfe-b9d6a2762dd2'	System	29 Jul 2020 15:17:42
User entered 'No interference with activity (1)'	System	29 Jul 2020 15:17:42



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:16:58', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '86f4dee4-cac9-4a4f-bbfe-b9d6a2762dd2'	System	29 Jul 2020 15:17:42
User entered 'No interference with activity (1)'	System	29 Jul 2020 15:17:42



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:17:04', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '86f4dee4-cac9-4a4f-bbfe-b9d6a2762dd2' User entered 'None (0)'	System	29 Jul 2020 15:17:42
	System	29 Jul 2020 15:17:42



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:17:08', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '86f4dee4-cac9-4a4f-bbfe-b9d6a2762dd2'	System	29 Jul 2020 15:17:42
User entered 'None (0)'	System	29 Jul 2020 15:17:42



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:17:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '86f4dee4-cac9-4a4f-bbfe-b9d6a2762dd2'	System	29 Jul 2020 15:17:42
User entered 'No (N)'	System	29 Jul 2020 15:17:42



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Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-29T08:17:38', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '86f4dee4-cac9-4a4f-bbfe-b9d6a2762dd2' User entered '29 Jul 2020 08:17'	System	29 Jul 2020 15:17:42
	System	29 Jul 2020 15:17:42



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Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Jul 2020 20:47'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '29 Jul 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 2'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:00:49', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '49eb9fc8-9232-4cca-9a44-4e23db7b2942'	System	30 Jul 2020 13:01:31
User entered 'None (0)'	System	30 Jul 2020 13:01:31



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:00:58', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '49eb9fc8-9232-4cca-9a44-4e23db7b2942'	System	30 Jul 2020 13:01:31
User entered 'None (0)'	System	30 Jul 2020 13:01:31



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:01:01', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '49eb9fc8-9232-4cca-9a44-4e23db7b2942'	System	30 Jul 2020 13:01:31
User entered 'None (0)'	System	30 Jul 2020 13:01:31



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:01:06', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '49eb9fc8-9232-4cca-9a44-4e23db7b2942' User entered 'None (0)'	System	30 Jul 2020 13:01:31
	System	30 Jul 2020 13:01:31



**US3262027**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:15:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:01:09', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '49eb9fc8-9232-4cca-9a44-4e23db7b2942' User entered 'None (0)'	System	30 Jul 2020 13:01:31
	System	30 Jul 2020 13:01:31



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:01:12', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '49eb9fc8-9232-4cca-9a44-4e23db7b2942' User entered 'None (0)'	System	30 Jul 2020 13:01:31
	System	30 Jul 2020 13:01:31



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:01:23', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '49eb9fc8-9232-4cca-9a44-4e23db7b2942'	System	30 Jul 2020 13:01:31
User entered 'No (N)'	System	30 Jul 2020 13:01:31



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-30T06:01:28', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '49eb9fc8-9232-4cca-9a44-4e23db7b2942'	System	30 Jul 2020 13:01:31
User entered '30 Jul 2020 06:01'	System	30 Jul 2020 13:01:31



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '29 Jul 2020 12:00'	System	29 Jul 2020 00:20:56



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 00:20:56



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 3'	System	29 Jul 2020 00:20:56



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:30', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a1523667-28f0-42fb-8b90-4285bc17bd22'	System	31 Jul 2020 17:15:02
User entered 'None (0)'	System	31 Jul 2020 17:15:02



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:35', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a1523667-28f0-42fb-8b90-4285bc17bd22' User entered 'None (0)'	System	31 Jul 2020 17:15:02
	System	31 Jul 2020 17:15:02



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:39', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a1523667-28f0-42fb-8b90-4285bc17bd22' User entered 'None (0)'	System	31 Jul 2020 17:15:02
	System	31 Jul 2020 17:15:02



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:42', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a1523667-28f0-42fb-8b90-4285bc17bd22' User entered 'None (0)'	System	31 Jul 2020 17:15:02
	System	31 Jul 2020 17:15:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:47', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a1523667-28f0-42fb-8b90-4285bc17bd22' User entered 'None (0)'	System	31 Jul 2020 17:15:02
	System	31 Jul 2020 17:15:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:52', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a1523667-28f0-42fb-8b90-4285bc17bd22' User entered 'None (0)'	System	31 Jul 2020 17:15:02
	System	31 Jul 2020 17:15:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a1523667-28f0-42fb-8b90-4285bc17bd22'	System	31 Jul 2020 17:15:02
User entered 'No (N)'	System	31 Jul 2020 17:15:02



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-07-31T10:14:59', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a1523667-28f0-42fb-8b90-4285bc17bd22' User entered '31 Jul 2020 10:14'	System	31 Jul 2020 17:15:02
	System	31 Jul 2020 17:15:02



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 4'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:42', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2d20fde0-12af-4a0b-b01d-4003b92bc69d' User entered 'None (0)'	System	01 Aug 2020 17:14:15
	System	01 Aug 2020 17:14:15



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:46', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2d20fde0-12af-4a0b-b01d-4003b92bc69d' User entered 'None (0)'	System	01 Aug 2020 17:14:15
	System	01 Aug 2020 17:14:15



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:49', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2d20fde0-12af-4a0b-b01d-4003b92bc69d' User entered 'None (0)'	System	01 Aug 2020 17:14:15
	System	01 Aug 2020 17:14:15



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:53', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2d20fde0-12af-4a0b-b01d-4003b92bc69d' User entered 'None (0)'	System	01 Aug 2020 17:14:15
	System	01 Aug 2020 17:14:15



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2d20fde0-12af-4a0b-b01d-4003b92bc69d' User entered 'None (0)'	System	01 Aug 2020 17:14:15
	System	01 Aug 2020 17:14:15



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:13:58', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2d20fde0-12af-4a0b-b01d-4003b92bc69d' User entered 'None (0)'	System	01 Aug 2020 17:14:15
	System	01 Aug 2020 17:14:15



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:14:08', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2d20fde0-12af-4a0b-b01d-4003b92bc69d' User entered 'No (N)'	System	01 Aug 2020 17:14:15
	System	01 Aug 2020 17:14:15



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-01T10:14:13', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2d20fde0-12af-4a0b-b01d-4003b92bc69d' User entered '01 Aug 2020 10:14'	System	01 Aug 2020 17:14:15
	System	01 Aug 2020 17:14:15



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 5'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 6'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:15', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '20c4460e-310c-4ee9-bd78-9ff74f58b779' User entered 'None (0)'	System	02 Aug 2020 19:01:40
	System	02 Aug 2020 19:01:40



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '20c4460e-310c-4ee9-bd78-9ff74f58b779' User entered 'None (0)'	System	02 Aug 2020 19:01:40
	System	02 Aug 2020 19:01:40



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:22', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '20c4460e-310c-4ee9-bd78-9ff74f58b779' User entered 'None (0)'	System	02 Aug 2020 19:01:40
	System	02 Aug 2020 19:01:40



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:25', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '20c4460e-310c-4ee9-bd78-9ff74f58b779' User entered 'None (0)'	System	02 Aug 2020 19:01:40
	System	02 Aug 2020 19:01:40



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:28', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '20c4460e-310c-4ee9-bd78-9ff74f58b779' User entered 'None (0)'	System	02 Aug 2020 19:01:40
	System	02 Aug 2020 19:01:40



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:31', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '20c4460e-310c-4ee9-bd78-9ff74f58b779' User entered 'None (0)'	System	02 Aug 2020 19:01:40
	System	02 Aug 2020 19:01:40



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:34', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '20c4460e-310c-4ee9-bd78-9ff74f58b779' User entered 'No (N)'	System	02 Aug 2020 19:01:40
	System	02 Aug 2020 19:01:40



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-02T12:01:38', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '20c4460e-310c-4ee9-bd78-9ff74f58b779' User entered '02 Aug 2020 12:01'	System	02 Aug 2020 19:01:40
	System	02 Aug 2020 19:01:40



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 7'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-04T00:00:11', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fbab5518-7ff8-498d-a2ba-3aabe145dacc' User entered 'None (0)'	System	04 Aug 2020 07:00:41
	System	04 Aug 2020 07:00:41



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-04T00:00:16', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fbab5518-7ff8-498d-a2ba-3aabe145dacc' User entered 'None (0)'	System	04 Aug 2020 07:00:41
	System	04 Aug 2020 07:00:41



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-04T00:00:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fbab5518-7ff8-498d-a2ba-3aabe145dacc' User entered 'None (0)'	System	04 Aug 2020 07:00:41
	System	04 Aug 2020 07:00:41



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-04T00:00:21', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fbab5518-7ff8-498d-a2ba-3aabe145dacc' User entered 'None (0)'	System	04 Aug 2020 07:00:41
	System	04 Aug 2020 07:00:41



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-04T00:00:24', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fbab5518-7ff8-498d-a2ba-3aabe145dacc' User entered 'None (0)'	System	04 Aug 2020 07:00:41
	System	04 Aug 2020 07:00:41



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-04T00:00:27', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fbab5518-7ff8-498d-a2ba-3aabe145dacc' User entered 'None (0)'	System	04 Aug 2020 07:00:41
	System	04 Aug 2020 07:00:41



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-04T00:00:31', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fbab5518-7ff8-498d-a2ba-3aabe145dacc'	System	04 Aug 2020 07:00:41
User entered 'No (N)'	System	04 Aug 2020 07:00:41



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-08-04T00:00:37', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fbab5518-7ff8-498d-a2ba-3aabe145dacc' User entered '04 Aug 2020 00:00'	System	04 Aug 2020 07:00:41
	System	04 Aug 2020 07:00:41



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 00:20:56



US3262027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 00:20:56



**US3262027**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:09



**US3262027**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '04 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:09



US3262027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:09



US3262027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:09



US3262027

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:16



US3262027

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'I'	System	13 Aug 2020 01:51:16



US3262027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:37



**US3262027**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:37



**US3262027**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:37



US3262027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:37



US3262027

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 01:51:44



US3262027

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'I'	System	13 Aug 2020 01:51:44



US3262027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Aug 2020 17:47:24



US3262027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '20 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	26 Aug 2020 17:47:24
	(b) (4)	



US3262027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	26 Aug 2020 17:47:24



US3262027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	26 Aug 2020 17:47:24
	(b) (4)	



US3262027

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	26 Aug 2020 17:47:31



**US3262027**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:15:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'I'	System	26 Aug 2020 17:47:31



US3262027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:43:39



US3262027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User closed query 'Per CDM: Visit date noted is out of window, however AE page needs to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM).	(b) (4)	
Query 'Per CDM: Visit date noted is out of window, however AE page needs to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. answered with 'Reviewed date in source and confirmed correct as recorded.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 09:56:05
Query 'Per CDM: Visit date noted is out of window, however AE page needs to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. answered with 'Reviewed date in source and confirmed correct as recorded.' (Site from DM).	Alia Bober (b) (4)	03 Feb 2021 17:26:47
	(b) (4)	
User opened query 'Per CDM: Visit date noted is out of window, however AE page needs to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 20:49:16
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 11:30:25
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'correct as is ' (Site from System).	Daisy Langarica (b) (4)	22 Sep 2020 14:43:46
	(b) (4)	
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Sep 2020 14:43:39
User entered '21 Sep 2020'	Daisy Langarica (b) (4)	22 Sep 2020 14:43:39
	(b) (4)	



US3262027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[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 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	22 Sep 2020 14:43:39



**US3262027**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'VISIT2'	System	22 Sep 2020 14:43:39



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4)	22 Sep 2020 14:45:29
	(b) (4)	



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '21 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	22 Sep 2020 14:47:16
User entered '09:50' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	22 Sep 2020 14:47:16
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	22 Sep 2020 14:45:29
User entered '10:50'	Daisy Langarica (b) (4) (b) (4)	22 Sep 2020 14:45:29



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '21 Sep 2020 09:50'	System	22 Sep 2020 14:47:16
User entered '21 Sep 2020 10:50'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '97.3' F	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29
	(b) (4)	



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered empty.	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '57'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'bpm'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '12'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'breaths/min'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '113'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '73'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4) (b) (4)	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '21 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	22 Sep 2020 14:47:16
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	22 Sep 2020 14:45:29
User entered '10:41'	Daisy Langarica (b) (4) (b) (4)	22 Sep 2020 14:45:29



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '21 Sep 2020 10:41'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '97.9' F	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29
	(b) (4)	



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered empty.	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29
	(b) (4)	



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '61'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'bpm'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '12'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'breaths/min'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '109'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '79'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	22 Sep 2020 14:45:29



US3262027

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:43:56



US3262027

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '21 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:43:56



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	21 Sep 2020 17:40:58



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Sep 2020 17:40:58
	(b) (4)	



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

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 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Sep 2020 17:40:58
	(b) (4)	



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 17:40:58



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '21 Sep 2020'	(b) (4) Daisy Langarica (b) (4) (b) (4)	21 Sep 2020 17:40:58



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '10:11'	(b) (4) Daisy Langarica (b) (4)	21 Sep 2020 17:40:58



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '21 Sep 2020 10:11'	System	21 Sep 2020 17:40:58



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langerica (b) (4) (b) (4)	21 Sep 2020 17:40:58



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'ONCE'	System	21 Sep 2020 17:40:58



US3262027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:15:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 17:40:58



US3262027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:44:14



US3262027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '21 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:44:14



US3262027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '09:55' reason for change: Data Entry Error	(b) (4)	
	Daisy Langarica (b) (4)	22 Sep 2020 14:47:29
	(b) (4)	
User entered '10:55'	Daisy Langarica (b) (4)	22 Sep 2020 14:44:14
	(b) (4)	



**US3262027**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '21 Sep 2020 09:55'	System	22 Sep 2020 14:47:29
User entered '21 Sep 2020 10:55'	System	22 Sep 2020 14:44:14



US3262027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:15:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '21 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:44:26



US3262027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Daisy Langarica (b) (4)	22 Sep 2020 14:44:26



US3262027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:44:26



US3262027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '09:52' reason for change: Data Entry Error	(b) (4)	
	Daisy Langarica (b) (4)	22 Sep 2020 14:47:37
User entered '10:52'	(b) (4)	
	Daisy Langarica (b) (4)	22 Sep 2020 14:44:26
	(b) (4)	



US3262027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '21 Sep 2020 09:52'	System	22 Sep 2020 14:47:37
User entered '21 Sep 2020 10:52'	System	22 Sep 2020 14:44:26



US3262027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Daisy Langarica (b) (4)	22 Sep 2020 14:44:26



US3262027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:44:26



US3262027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:15:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	22 Sep 2020 14:44:26



**US3262027**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered empty.	System	22 Sep 2020 14:44:26



US3262027

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langerica (b) (4)	22 Sep 2020 14:44:29



**US3262027**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:15:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'I'	System	22 Sep 2020 14:44:29



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:45:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9c82455e-b4e7-4d2a-ab38-31cdec7c7797' User entered 'Yes (Y)'	System	21 Sep 2020 17:46:52
	System	21 Sep 2020 17:46:52



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:46:32', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9c82455e-b4e7-4d2a-ab38-31cdec7c7797' User entered '97.8'	System	21 Sep 2020 17:46:52
	System	21 Sep 2020 17:46:52



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:46:40', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9c82455e-b4e7-4d2a-ab38-31cdec7c7797'	System	21 Sep 2020 17:46:52
User entered 'No (N)'	System	21 Sep 2020 17:46:52



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:46:49', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9c82455e-b4e7-4d2a-ab38-31cdec7c7797' User entered '21 Sep 2020 10:46'	System	21 Sep 2020 17:46:52
	System	21 Sep 2020 17:46:52



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '21 Sep 2020 10:31'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '21 Sep 2020 13:01'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:10:42', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'd3e60d49-44c5-4d51-ab82-90053e8f77b9' User entered 'Yes (Y)'	System	22 Sep 2020 17:12:38
	System	22 Sep 2020 17:12:38



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:10:58', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'd3e60d49-44c5-4d51-ab82-90053e8f77b9' User entered '98.2'	System	22 Sep 2020 17:12:38
	System	22 Sep 2020 17:12:38



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:12:26', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'd3e60d49-44c5-4d51-ab82-90053e8f77b9' User entered 'Yes (Y)'	System	22 Sep 2020 17:12:38
	System	22 Sep 2020 17:12:38



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PER PIs note subject did not report any AE's nor Conmeds see source ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 10:47:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:12:07', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'd3e60d49-44c5-4d51-ab82-90053e8f77b9' User entered '1'	Daisy Langarica (b) (4) (b) (4)	23 Nov 2020 18:22:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Sep 2020 17:12:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:12:07', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'd3e60d49-44c5-4d51-ab82-90053e8f77b9' User entered '1'	System	22 Sep 2020 17:12:38
User entered '1'	System	22 Sep 2020 17:12:38



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PER PIs note subject did not report any AE's nor Conmeds see source ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 10:47:30
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Daisy Langarica (b) (4)	23 Nov 2020 18:22:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:12:07', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'd3e60d49-44c5-4d51-ab82-90053e8f77b9'	(b) (4)	
User entered '1'	System	22 Sep 2020 17:12:38



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Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:12:32', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'd3e60d49-44c5-4d51-ab82-90053e8f77b9' User entered '22 Sep 2020 10:12'	System	22 Sep 2020 17:12:38
	System	22 Sep 2020 17:12:38



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '21 Sep 2020 13:56'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 2'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:06:52', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f217ebc9-0c39-409b-99e0-883ca1f2b9a9' User entered 'Yes (Y)'	System	22 Sep 2020 19:07:33
	System	22 Sep 2020 19:07:33



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f217ebc9-0c39-409b-99e0-883ca1f2b9a9' User entered '98.2'	System	22 Sep 2020 19:07:33
	System	22 Sep 2020 19:07:33



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:07', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f217ebc9-0c39-409b-99e0-883ca1f2b9a9'	System	22 Sep 2020 19:07:33
User entered 'Yes (Y)'	System	22 Sep 2020 19:07:33



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PER PIs note subject did not report any AE's nor Conmeds see source ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 10:47:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:14', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f217ebc9-0c39-409b-99e0-883ca1f2b9a9' User entered '1'	Daisy Langarica (b) (4) (b) (4)	23 Nov 2020 18:22:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Sep 2020 19:07:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:14', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f217ebc9-0c39-409b-99e0-883ca1f2b9a9' User entered '1'	System	22 Sep 2020 19:07:33
User entered '1'	System	22 Sep 2020 19:07:33



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:14', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f217ebc9-0c39-409b-99e0-883ca1f2b9a9' User entered '0'	System	22 Sep 2020 19:07:33
	System	22 Sep 2020 19:07:33



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:30', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f217ebc9-0c39-409b-99e0-883ca1f2b9a9' User entered '22 Sep 2020 12:07'	System	22 Sep 2020 19:07:33
	System	22 Sep 2020 19:07:33



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 3'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:58:46', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '64fb42f5-fe65-470f-b5b2-d61d1efb58bb' User entered 'Yes (Y)'	System	24 Sep 2020 02:59:08
	System	24 Sep 2020 02:59:08



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:58:54', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '64fb42f5-fe65-470f-b5b2-d61d1efb58bb' User entered '97.8'	System	24 Sep 2020 02:59:08
	System	24 Sep 2020 02:59:08



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:58:58', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '64fb42f5-fe65-470f-b5b2-d61d1efb58bb'	System	24 Sep 2020 02:59:08
User entered 'No (N)'	System	24 Sep 2020 02:59:08



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:04', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '64fb42f5-fe65-470f-b5b2-d61d1efb58bb' User entered '23 Sep 2020 19:59'	System	24 Sep 2020 02:59:08
	System	24 Sep 2020 02:59:08



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 4'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:48:59', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '64a62474-d2fa-462f-8a0e-055448051c76'	System	25 Sep 2020 05:49:25
User entered 'Yes (Y)'	System	25 Sep 2020 05:49:25



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:49:09', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '64a62474-d2fa-462f-8a0e-055448051c76' User entered '97.9'	System	25 Sep 2020 05:49:25
	System	25 Sep 2020 05:49:25



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:49:14', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '64a62474-d2fa-462f-8a0e-055448051c76'	System	25 Sep 2020 05:49:25
User entered 'No (N)'	System	25 Sep 2020 05:49:25



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:49:24', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '64a62474-d2fa-462f-8a0e-055448051c76' User entered '24 Sep 2020 22:49'	System	25 Sep 2020 05:49:25
	System	25 Sep 2020 05:49:25



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 5'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:58:05', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '3a3e071d-089d-4507-89bd-06f8a8705573' User entered 'Yes (Y)'	System	26 Sep 2020 07:58:25
	System	26 Sep 2020 07:58:25



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAF)', Time: '2020-09-26T00:58:13', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '3a3e071d-089d-4507-89bd-06f8a8705573' User entered '97.6'	System	26 Sep 2020 07:58:25
	System	26 Sep 2020 07:58:25



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994ED AFC)', Time: '2020-09-26T00:58:18', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '3a3e071d-089d-4507-89bd-06f8a8705573' User entered 'No (N)'	System	26 Sep 2020 07:58:25
	System	26 Sep 2020 07:58:25



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:58:23', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '3a3e071d-089d-4507-89bd-06f8a8705573' User entered '26 Sep 2020 00:58'	System	26 Sep 2020 07:58:25
	System	26 Sep 2020 07:58:25



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 6'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:09:34', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'da4ea25e-7eb8-4757-8fb8-ddc8435afa63' User entered 'Yes (Y)'	System	27 Sep 2020 13:09:54
	System	27 Sep 2020 13:09:54



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:09:44', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'da4ea25e-7eb8-4757-8fb8-ddc8435afa63' User entered '97.8'	System	27 Sep 2020 13:09:54
	System	27 Sep 2020 13:09:54



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:09:47', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'da4ea25e-7eb8-4757-8fb8-ddc8435afa63'	System	27 Sep 2020 13:09:54
User entered 'No (N)'	System	27 Sep 2020 13:09:54



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:09:53', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'da4ea25e-7eb8-4757-8fb8-ddc8435afa63' User entered '27 Sep 2020 06:09'	System	27 Sep 2020 13:09:54
	System	27 Sep 2020 13:09:54



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 7'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:56:52', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '26fad0b9-8875-45fd-a58e-99693fca4109' User entered 'Yes (Y)'	System	28 Sep 2020 09:57:11
	System	28 Sep 2020 09:57:11



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '26fad0b9-8875-45fd-a58e-99693fca4109' User entered '97.8'	System	28 Sep 2020 09:57:11
	System	28 Sep 2020 09:57:11



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:04', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '26fad0b9-8875-45fd-a58e-99693fca4109'	System	28 Sep 2020 09:57:11
User entered 'No (N)'	System	28 Sep 2020 09:57:11



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:08', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '26fad0b9-8875-45fd-a58e-99693fca4109' User entered '28 Sep 2020 02:57'	System	28 Sep 2020 09:57:11
	System	28 Sep 2020 09:57:11



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:47:01', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '15bc47b9-cff3-4341-8258-7e1d8839bfdc'	System	21 Sep 2020 17:48:07
User entered 'None (1)'	System	21 Sep 2020 17:48:07



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:47:20', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '15bc47b9-cff3-4341-8258-7e1d8839bfdc' User entered 'No (N)'	System	21 Sep 2020 17:48:07
	System	21 Sep 2020 17:48:07



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:47:26', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '15bc47b9-cff3-4341-8258-7e1d8839bfdc' User entered 'No (N)'	System	21 Sep 2020 17:48:07
	System	21 Sep 2020 17:48:07



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:47:49', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '15bc47b9-cff3-4341-8258-7e1d8839bfdc'	System	21 Sep 2020 17:48:07
User entered 'None (1)'	System	21 Sep 2020 17:48:07



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:48:04', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '15bc47b9-cff3-4341-8258-7e1d8839bfdc' User entered '21 Sep 2020 10:48'	System	21 Sep 2020 17:48:07
	System	21 Sep 2020 17:48:07



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '21 Sep 2020 10:31'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '21 Sep 2020 13:01'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-09-22T10:12:55', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c7a14283-5e1b-4849-9b5c-95185c287cff'	System	22 Sep 2020 17:15:20
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		22 Sep 2020 17:15:20



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:13:45', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c7a14283-5e1b-4849-9b5c-95185c287cff' User entered 'No (N)'	System	22 Sep 2020 17:15:20
	System	22 Sep 2020 17:15:20



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:14:08', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c7a14283-5e1b-4849-9b5c-95185c287cff' User entered 'No (N)'	System	22 Sep 2020 17:15:20
	System	22 Sep 2020 17:15:20



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:14:20', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c7a14283-5e1b-4849-9b5c-95185c287cff' User entered 'None (1)'	System	22 Sep 2020 17:15:20
	System	22 Sep 2020 17:15:20



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:15:18', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c7a14283-5e1b-4849-9b5c-95185c287cff' User entered '22 Sep 2020 10:15'	System	22 Sep 2020 17:15:20
	System	22 Sep 2020 17:15:20



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '21 Sep 2020 13:56'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 2'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:43', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5fe23363-5971-4ee3-a383-d2b57535f9a2'	System	22 Sep 2020 19:08:09
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		22 Sep 2020 19:08:09



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:47', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5fe23363-5971-4ee3-a383-d2b57535f9a2'	System	22 Sep 2020 19:08:09
User entered 'No (N)'	System	22 Sep 2020 19:08:09



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:52', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5fe23363-5971-4ee3-a383-d2b57535f9a2'	System	22 Sep 2020 19:08:09
User entered 'No (N)'	System	22 Sep 2020 19:08:09



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:07:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5fe23363-5971-4ee3-a383-d2b57535f9a2'	System	22 Sep 2020 19:08:09
User entered 'None (1)'	System	22 Sep 2020 19:08:09



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:08:05', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5fe23363-5971-4ee3-a383-d2b57535f9a2' User entered '22 Sep 2020 12:08'	System	22 Sep 2020 19:08:09
	System	22 Sep 2020 19:08:09



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 3'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:10', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c4236fcf-55eb-4bc3-915c-a18f467ea098'	System	24 Sep 2020 02:59:34
User entered 'None (1)'	System	24 Sep 2020 02:59:34



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:14', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c4236fcf-55eb-4bc3-915c-a18f467ea098'	System	24 Sep 2020 02:59:34
User entered 'No (N)'	System	24 Sep 2020 02:59:34



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:23', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c4236fcf-55eb-4bc3-915c-a18f467ea098'	System	24 Sep 2020 02:59:34
User entered 'No (N)'	System	24 Sep 2020 02:59:34



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-09-23T19:59:26', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c4236fcf-55eb-4bc3-915c-a18f467ea098'	System	24 Sep 2020 02:59:34
User entered 'None (1)'	System	24 Sep 2020 02:59:34



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:31', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c4236fcf-55eb-4bc3-915c-a18f467ea098'	System	24 Sep 2020 02:59:34
User entered '23 Sep 2020 19:59'	System	24 Sep 2020 02:59:34



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 4'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-09-24T22:49:35', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9055ad5f-b122-4079-88fa-e43aa4cb6669'	System	25 Sep 2020 05:49:59
User entered 'None (1)'	System	25 Sep 2020 05:49:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:49:39', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9055ad5f-b122-4079-88fa-e43aa4cb6669'	System	25 Sep 2020 05:49:59
User entered 'No (N)'	System	25 Sep 2020 05:49:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-09-24T22:49:45', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9055ad5f-b122-4079-88fa-e43aa4cb6669'	System	25 Sep 2020 05:49:59
User entered 'No (N)'	System	25 Sep 2020 05:49:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:49:49', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9055ad5f-b122-4079-88fa-e43aa4cb6669'	System	25 Sep 2020 05:49:59
User entered 'None (1)'	System	25 Sep 2020 05:49:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:49:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9055ad5f-b122-4079-88fa-e43aa4cb6669'	System	25 Sep 2020 05:49:59
User entered '24 Sep 2020 22:49'	System	25 Sep 2020 05:49:59



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 5'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:58:30', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '7e2db8cb-7181-4f5f-b3b5-08dcf1747663'	System	26 Sep 2020 07:58:54
User entered 'None (1)'	System	26 Sep 2020 07:58:54



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:58:33', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '7e2db8cb-7181-4f5f-b3b5-08dcf1747663'	System	26 Sep 2020 07:58:54
User entered 'No (N)'	System	26 Sep 2020 07:58:54



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:58:37', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '7e2db8cb-7181-4f5f-b3b5-08dcf1747663'	System	26 Sep 2020 07:58:54
User entered 'No (N)'	System	26 Sep 2020 07:58:54



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:58:42', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '7e2db8cb-7181-4f5f-b3b5-08dcf1747663'	System	26 Sep 2020 07:58:54
User entered 'None (1)'	System	26 Sep 2020 07:58:54



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:58:51', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '7e2db8cb-7181-4f5f-b3b5-08dcf1747663' User entered '26 Sep 2020 00:58'	System	26 Sep 2020 07:58:54
	System	26 Sep 2020 07:58:54



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 6'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:09:57', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a0805409-4bf7-48f3-a71e-eb681f38da8d'	System	27 Sep 2020 13:10:16
User entered 'None (1)'	System	27 Sep 2020 13:10:16



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a0805409-4bf7-48f3-a71e-eb681f38da8d' User entered 'No (N)'	System	27 Sep 2020 13:10:16
	System	27 Sep 2020 13:10:16



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-09-27T06:10:03', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a0805409-4bf7-48f3-a71e-eb681f38da8d'	System	27 Sep 2020 13:10:16
User entered 'No (N)'	System	27 Sep 2020 13:10:16



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:09', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a0805409-4bf7-48f3-a71e-eb681f38da8d' User entered 'None (1)'	System	27 Sep 2020 13:10:16
	System	27 Sep 2020 13:10:16



**US3262027**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:15:03**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:13', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a0805409-4bf7-48f3-a71e-eb681f38da8d' User entered '27 Sep 2020 06:10'	System	27 Sep 2020 13:10:16
	System	27 Sep 2020 13:10:16



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 7'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-09-28T02:57:15', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c94a97ef-56ca-4abf-8528-f00ea1be66fd'	System	28 Sep 2020 09:57:30
User entered 'None (1)'	System	28 Sep 2020 09:57:30



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c94a97ef-56ca-4abf-8528-f00ea1be66fd' User entered 'No (N)'	System	28 Sep 2020 09:57:30
	System	28 Sep 2020 09:57:30



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-09-28T02:57:22', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c94a97ef-56ca-4abf-8528-f00ea1be66fd' User entered 'No (N)'	System	28 Sep 2020 09:57:30
	System	28 Sep 2020 09:57:30



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-09-28T02:57:25', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c94a97ef-56ca-4abf-8528-f00ea1be66fd'	System	28 Sep 2020 09:57:30
User entered 'None (1)'	System	28 Sep 2020 09:57:30



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:28', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c94a97ef-56ca-4abf-8528-f00ea1be66fd' User entered '28 Sep 2020 02:57'	System	28 Sep 2020 09:57:30
	System	28 Sep 2020 09:57:30



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:50:40', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '97efbbac-e0fe-4885-ad36-8a2f4009280c' User entered 'None (0)'	System	21 Sep 2020 17:51:20
	System	21 Sep 2020 17:51:20



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:50:45', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '97efbbac-e0fe-4885-ad36-8a2f4009280c' User entered 'None (0)'	System	21 Sep 2020 17:51:20
	System	21 Sep 2020 17:51:20



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:50:50', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '97efbbac-e0fe-4885-ad36-8a2f4009280c' User entered 'None (0)'	System	21 Sep 2020 17:51:20
	System	21 Sep 2020 17:51:20



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:50:53', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '97efbbac-e0fe-4885-ad36-8a2f4009280c' User entered 'None (0)'	System	21 Sep 2020 17:51:20
	System	21 Sep 2020 17:51:20



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:50:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '97efbbac-e0fe-4885-ad36-8a2f4009280c' User entered 'None (0)'	System	21 Sep 2020 17:51:20
	System	21 Sep 2020 17:51:20



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:50:59', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '97efbbac-e0fe-4885-ad36-8a2f4009280c' User entered 'None (0)'	System	21 Sep 2020 17:51:20
	System	21 Sep 2020 17:51:20



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:51:08', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '97efbbac-e0fe-4885-ad36-8a2f4009280c' User entered 'No (N)'	System	21 Sep 2020 17:51:20
	System	21 Sep 2020 17:51:20



**US3262027**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:15:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-21T10:51:15', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '97efbbac-e0fe-4885-ad36-8a2f4009280c' User entered '21 Sep 2020 10:51'	System	21 Sep 2020 17:51:20
	System	21 Sep 2020 17:51:20



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '21 Sep 2020 10:31'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '21 Sep 2020 13:01'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:15:26', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '172ed28f-4b38-440e-9d08-4472433b9bb6' User entered 'None (0)'	System	22 Sep 2020 17:16:39
	System	22 Sep 2020 17:16:39



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:15:31', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '172ed28f-4b38-440e-9d08-4472433b9bb6' User entered 'None (0)'	System	22 Sep 2020 17:16:39
	System	22 Sep 2020 17:16:39



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:15:45', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '172ed28f-4b38-440e-9d08-4472433b9bb6'	System	22 Sep 2020 17:16:39
User entered 'No interference with activity (1)'	System	22 Sep 2020 17:16:39



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-09-22T10:15:57', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '172ed28f-4b38-440e-9d08-4472433b9bb6'	System	22 Sep 2020 17:16:39
User entered 'No interference with activity (1)'	System	22 Sep 2020 17:16:39



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:16:02', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '172ed28f-4b38-440e-9d08-4472433b9bb6' User entered 'None (0)'	System	22 Sep 2020 17:16:39
	System	22 Sep 2020 17:16:39



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:16:08', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '172ed28f-4b38-440e-9d08-4472433b9bb6' User entered 'None (0)'	System	22 Sep 2020 17:16:39
	System	22 Sep 2020 17:16:39



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:16:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '172ed28f-4b38-440e-9d08-4472433b9bb6'	System	22 Sep 2020 17:16:39
User entered 'No (N)'	System	22 Sep 2020 17:16:39



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T10:16:35', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '172ed28f-4b38-440e-9d08-4472433b9bb6'	System	22 Sep 2020 17:16:39
User entered '22 Sep 2020 10:16'	System	22 Sep 2020 17:16:39



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '21 Sep 2020 13:56'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 2'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:08:10', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f972dce3-93ca-48a9-be00-d0bca18bbd20' User entered 'None (0)'	System	22 Sep 2020 19:09:06
	System	22 Sep 2020 19:09:06



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:08:13', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f972dce3-93ca-48a9-be00-d0bca18bbd20' User entered 'None (0)'	System	22 Sep 2020 19:09:06
	System	22 Sep 2020 19:09:06



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:08:46', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f972dce3-93ca-48a9-be00-d0bca18bbd20' User entered 'None (0)'	System	22 Sep 2020 19:09:06
	System	22 Sep 2020 19:09:06



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:08:25', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f972dce3-93ca-48a9-be00-d0bca18bbd20' User entered 'None (0)'	System	22 Sep 2020 19:09:06
	System	22 Sep 2020 19:09:06



**US3262027**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:15:03**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:08:28', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f972dce3-93ca-48a9-be00-d0bca18bbd20' User entered 'None (0)'	System	22 Sep 2020 19:09:06
	System	22 Sep 2020 19:09:06



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:08:30', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f972dce3-93ca-48a9-be00-d0bca18bbd20' User entered 'None (0)'	System	22 Sep 2020 19:09:06
	System	22 Sep 2020 19:09:06



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:08:34', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f972dce3-93ca-48a9-be00-d0bca18bbd20' User entered 'No (N)'	System	22 Sep 2020 19:09:06
	System	22 Sep 2020 19:09:06



**US3262027**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:15:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-22T12:09:02', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f972dce3-93ca-48a9-be00-d0bca18bbd20' User entered '22 Sep 2020 12:09'	System	22 Sep 2020 19:09:06
	System	22 Sep 2020 19:09:06



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 3'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:35', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'faebf4c1-e76c-4edd-a162-7bbafb2b373c' User entered 'None (0)'	System	24 Sep 2020 02:59:58
	System	24 Sep 2020 02:59:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:38', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'faebf4c1-e76c-4edd-a162-7bbafb2b373c' User entered 'None (0)'	System	24 Sep 2020 02:59:58
	System	24 Sep 2020 02:59:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:41', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'faebf4c1-e76c-4edd-a162-7bbafb2b373c' User entered 'None (0)'	System	24 Sep 2020 02:59:58
	System	24 Sep 2020 02:59:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:43', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'faebf4c1-e76c-4edd-a162-7bbafb2b373c' User entered 'None (0)'	System	24 Sep 2020 02:59:58
	System	24 Sep 2020 02:59:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:46', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'faebf4c1-e76c-4edd-a162-7bbafb2b373c' User entered 'None (0)'	System	24 Sep 2020 02:59:58
	System	24 Sep 2020 02:59:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:48', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'faebf4c1-e76c-4edd-a162-7bbafb2b373c' User entered 'None (0)'	System	24 Sep 2020 02:59:58
	System	24 Sep 2020 02:59:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-23T19:59:53', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'faebf4c1-e76c-4edd-a162-7bbafb2b373c' User entered 'No (N)'	System	24 Sep 2020 02:59:58
	System	24 Sep 2020 02:59:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-09-23T19:59:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'faebf4c1-e76c-4edd-a162-7bbafb2b373c'	System	24 Sep 2020 02:59:58
User entered '23 Sep 2020 19:59'	System	24 Sep 2020 02:59:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 4'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:50:04', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'be5e042f-3500-4162-9238-05130e2e016a' User entered 'None (0)'	System	25 Sep 2020 05:50:38
	System	25 Sep 2020 05:50:38



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:50:10', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'be5e042f-3500-4162-9238-05130e2e016a' User entered 'None (0)'	System	25 Sep 2020 05:50:38
	System	25 Sep 2020 05:50:38



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:50:14', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'be5e042f-3500-4162-9238-05130e2e016a' User entered 'None (0)'	System	25 Sep 2020 05:50:38
	System	25 Sep 2020 05:50:38



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:50:18', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'be5e042f-3500-4162-9238-05130e2e016a' User entered 'None (0)'	System	25 Sep 2020 05:50:38
	System	25 Sep 2020 05:50:38



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:50:21', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'be5e042f-3500-4162-9238-05130e2e016a' User entered 'None (0)'	System	25 Sep 2020 05:50:38
	System	25 Sep 2020 05:50:38



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:50:24', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'be5e042f-3500-4162-9238-05130e2e016a' User entered 'None (0)'	System	25 Sep 2020 05:50:38
	System	25 Sep 2020 05:50:38



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:50:28', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'be5e042f-3500-4162-9238-05130e2e016a' User entered 'No (N)'	System	25 Sep 2020 05:50:38
	System	25 Sep 2020 05:50:38



**US3262027**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:15:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-24T22:50:33', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'be5e042f-3500-4162-9238-05130e2e016a' User entered '24 Sep 2020 22:50'	System	25 Sep 2020 05:50:38
	System	25 Sep 2020 05:50:38



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 5'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:58:56', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c203fcf0-f16e-4965-8015-d1698c7da01c' User entered 'None (0)'	System	26 Sep 2020 07:59:21
	System	26 Sep 2020 07:59:21



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:59:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c203fcf0-f16e-4965-8015-d1698c7da01c' User entered 'None (0)'	System	26 Sep 2020 07:59:21
	System	26 Sep 2020 07:59:21



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:59:03', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c203fcf0-f16e-4965-8015-d1698c7da01c' User entered 'None (0)'	System	26 Sep 2020 07:59:21
	System	26 Sep 2020 07:59:21



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:59:06', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c203fcf0-f16e-4965-8015-d1698c7da01c' User entered 'None (0)'	System	26 Sep 2020 07:59:21
	System	26 Sep 2020 07:59:21



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:59:09', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c203fcf0-f16e-4965-8015-d1698c7da01c' User entered 'None (0)'	System	26 Sep 2020 07:59:21
	System	26 Sep 2020 07:59:21



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:59:12', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c203fcf0-f16e-4965-8015-d1698c7da01c' User entered 'None (0)'	System	26 Sep 2020 07:59:21
	System	26 Sep 2020 07:59:21



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAF)', Time: '2020-09-26T00:59:15', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c203fcf0-f16e-4965-8015-d1698c7da01c'	System	26 Sep 2020 07:59:21
User entered 'No (N)'	System	26 Sep 2020 07:59:21



**US3262027**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:15:03**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-26T00:59:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'c203fcf0-f16e-4965-8015-d1698c7da01c' User entered '26 Sep 2020 00:59'	System	26 Sep 2020 07:59:21
	System	26 Sep 2020 07:59:21



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 6'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:19', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b43078c4-5916-4d6e-a755-74c5f0a4ee9c' User entered 'None (0)'	System	27 Sep 2020 13:10:51
	System	27 Sep 2020 13:10:51



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:24', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b43078c4-5916-4d6e-a755-74c5f0a4ee9c' User entered 'None (0)'	System	27 Sep 2020 13:10:51
	System	27 Sep 2020 13:10:51



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:27', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b43078c4-5916-4d6e-a755-74c5f0a4ee9c' User entered 'None (0)'	System	27 Sep 2020 13:10:51
	System	27 Sep 2020 13:10:51



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:30', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b43078c4-5916-4d6e-a755-74c5f0a4ee9c' User entered 'None (0)'	System	27 Sep 2020 13:10:51
	System	27 Sep 2020 13:10:51



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:32', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b43078c4-5916-4d6e-a755-74c5f0a4ee9c' User entered 'None (0)'	System	27 Sep 2020 13:10:51
	System	27 Sep 2020 13:10:51



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:35', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b43078c4-5916-4d6e-a755-74c5f0a4ee9c' User entered 'None (0)'	System	27 Sep 2020 13:10:51
	System	27 Sep 2020 13:10:51



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:38', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b43078c4-5916-4d6e-a755-74c5f0a4ee9c' User entered 'No (N)'	System	27 Sep 2020 13:10:51
	System	27 Sep 2020 13:10:51



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:10:47', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b43078c4-5916-4d6e-a755-74c5f0a4ee9c' User entered '27 Sep 2020 06:10'	System	27 Sep 2020 13:10:51
	System	27 Sep 2020 13:10:51



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	21 Sep 2020 17:40:58
User entered 'Day 7'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:32', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19f6711f-c2cc-49f6-ad74-5c03849d8ccb' User entered 'None (0)'	System	28 Sep 2020 09:57:54
	System	28 Sep 2020 09:57:54



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:34', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19f6711f-c2cc-49f6-ad74-5c03849d8ccb' User entered 'None (0)'	System	28 Sep 2020 09:57:54
	System	28 Sep 2020 09:57:54



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:37', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19f6711f-c2cc-49f6-ad74-5c03849d8ccb' User entered 'None (0)'	System	28 Sep 2020 09:57:54
	System	28 Sep 2020 09:57:54



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:39', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19f6711f-c2cc-49f6-ad74-5c03849d8ccb' User entered 'None (0)'	System	28 Sep 2020 09:57:54
	System	28 Sep 2020 09:57:54



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:41', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19f6711f-c2cc-49f6-ad74-5c03849d8ccb' User entered 'None (0)'	System	28 Sep 2020 09:57:54
	System	28 Sep 2020 09:57:54



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:43', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19f6711f-c2cc-49f6-ad74-5c03849d8ccb' User entered 'None (0)'	System	28 Sep 2020 09:57:54
	System	28 Sep 2020 09:57:54



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:47', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19f6711f-c2cc-49f6-ad74-5c03849d8ccb' User entered 'No (N)'	System	28 Sep 2020 09:57:54
	System	28 Sep 2020 09:57:54



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-28T02:57:50', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '19f6711f-c2cc-49f6-ad74-5c03849d8ccb' User entered '28 Sep 2020 02:57'	System	28 Sep 2020 09:57:54
	System	28 Sep 2020 09:57:54



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:40:58



US3262027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:15:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:40:58



US3262027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Atoya Adams (b) (4)	28 Sep 2020 19:57:18



US3262027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '28 Sep 2020'	(b) (4) Atoya Adams (b) (4) (b) (4)	28 Sep 2020 19:57:18



US3262027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Atoya Adams (b) (4) (b) (4)	28 Sep 2020 19:57:18



US3262027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	Atoya Adams (b) (4)	28 Sep 2020 19:57:18



US3262027

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Atoya Adams (b) (4)	28 Sep 2020 19:57:22



US3262027

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'I'	System	28 Sep 2020 19:57:22



US3262027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	08 Oct 2020 15:57:59



**US3262027**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '07 Oct 2020'	(b) (4) Daisy Langarica (b) (4) (b) (4)	08 Oct 2020 15:57:59



**US3262027**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	08 Oct 2020 15:57:59



US3262027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	08 Oct 2020 15:57:59
	(b) (4)	



US3262027

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	08 Oct 2020 15:58:03



**US3262027**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:15:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'I'	System	08 Oct 2020 15:58:03



US3262027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:47:27



**US3262027**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered '12 Oct 2020'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:47:27



US3262027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:47:27



US3262027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered empty.	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:47:27



US3262027

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:47:31



**US3262027**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:15:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'I'	System	19 Oct 2020 18:47:31



US3262027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:47:42



US3262027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '19 Oct 2020'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:47:42
	(b) (4)	



US3262027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[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 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	19 Oct 2020 18:47:42



US3262027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'VISIT3'	System	19 Oct 2020 18:47:42



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '19 Oct 2020'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:33
	(b) (4)	



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '08:35'	(b) (4) Daisy Langarica (b) (4) (b) (4)	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '19 Oct 2020 08:35'	System	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '97.7' F	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:33
	(b) (4)	



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered empty.	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:33
	(b) (4)	



**US3262027**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '66'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:33



**US3262027**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'bpm'	System	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '12'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'breaths/min'	System	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '118'	(b) (4) Daisy Langarica (b) (4) (b) (4)	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '83'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'mmHg'	System	19 Oct 2020 18:48:33



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25



US3262027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25



US3262027

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:47:46



US3262027

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered empty.	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:47:46



US3262027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Daisy Langerica (b) (4)	19 Oct 2020 18:48:03



US3262027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '19 Oct 2020'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:03
	(b) (4)	



**US3262027**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered '08:40'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:03



**US3262027**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:15:03**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered '19 Oct 2020 08:40'	System	19 Oct 2020 18:48:03



US3262027

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 21:19:26
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	19 Oct 2020 18:48:06



US3262027

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'I'	System	19 Oct 2020 18:48:06



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 64'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

[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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-09-27T06:11:03', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b1ea4c70-16f4-4752-aa51-5b8c3c4fdb6'	System	27 Sep 2020 13:11:26
User entered 'No (N)'	System	27 Sep 2020 13:11:26



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

Have you been exposed to someone with 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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:11:12', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b1ea4c70-16f4-4752-aa51-5b8c3c4fdb6'	System	27 Sep 2020 13:11:26
User entered 'No (N)'	System	27 Sep 2020 13:11:26



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-09-27T06:11:23', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b1ea4c70-16f4-4752-aa51-5b8c3c4fdb6'	System	27 Sep 2020 13:11:26
User entered '27 Sep 2020 06:11:23'	System	27 Sep 2020 13:11:26



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '27 Sep 2020 00:01'	System	29 Jul 2020 00:20:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '01 Oct 2020 23:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 71'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-10-04T04:07:34', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'ef9ce678-cb0a-470a-8226-fe84c8548371'	System	04 Oct 2020 11:07:48
User entered 'No (N)'	System	04 Oct 2020 11:07:48



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

Have you been exposed to someone with 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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-10-04T04:07:38', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'ef9ce678-cb0a-470a-8226-fe84c8548371'	System	04 Oct 2020 11:07:48
User entered 'No (N)'	System	04 Oct 2020 11:07:48



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-10-04T04:07:45', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'ef9ce678-cb0a-470a-8226-fe84c8548371' User entered '04 Oct 2020 04:07:45'	System	04 Oct 2020 11:07:48
	System	04 Oct 2020 11:07:48



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '04 Oct 2020 00:01'	System	29 Jul 2020 00:20:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '08 Oct 2020 23:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 78'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994ED AFC)', Time: '2020-10-11T08:01:27', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '402b56e1-c9ba-4785-a4e6-ba47d0e0f18c'	System	11 Oct 2020 15:01:42
User entered 'No (N)'	System	11 Oct 2020 15:01:42



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

Have you been exposed to someone with 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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-10-11T08:01:33', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '402b56e1-c9ba-4785-a4e6-ba47d0e0f18c'	System	11 Oct 2020 15:01:42
User entered 'No (N)'	System	11 Oct 2020 15:01:42



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-10-11T08:01:41', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '402b56e1-c9ba-4785-a4e6-ba47d0e0f18c' User entered '11 Oct 2020 08:01:41'	System	11 Oct 2020 15:01:42
	System	11 Oct 2020 15:01:42



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '11 Oct 2020 00:01'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '15 Oct 2020 23:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 92'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-10-29T12:25:13', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'e78e0c66-e5d9-4b42-9260-34531e327739'	System	29 Oct 2020 19:25:27
User entered 'No (N)'	System	29 Oct 2020 19:25:27



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

Have you been exposed to someone with 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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-10-29T12:25:17', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'e78e0c66-e5d9-4b42-9260-34531e327739'	System	29 Oct 2020 19:25:27
User entered 'No (N)'	System	29 Oct 2020 19:25:27



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-10-29T12:25:24', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'e78e0c66-e5d9-4b42-9260-34531e327739' User entered '29 Oct 2020 12:25:24'	System	29 Oct 2020 19:25:27
	System	29 Oct 2020 19:25:27



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '25 Oct 2020 00:01'	System	29 Jul 2020 00:20:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '29 Oct 2020 23:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 99'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994ED AFC)', Time: '2020-11-01T01:31:38', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f938a7e3-4042-491c-9580-9ee6a039952a' User entered 'No (N)'	System	01 Nov 2020 08:31:48
	System	01 Nov 2020 08:31:48



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

Have you been exposed to someone with 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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-11-01T01:31:42', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f938a7e3-4042-491c-9580-9ee6a039952a' User entered 'No (N)'	System	01 Nov 2020 08:31:48
	System	01 Nov 2020 08:31:48



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-11-01T01:31:47', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f938a7e3-4042-491c-9580-9ee6a039952a' User entered '01 Nov 2020 01:31:47'	System	01 Nov 2020 08:31:48
	System	01 Nov 2020 08:31:48



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '01 Nov 2020 00:01'	System	29 Jul 2020 00:20:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '05 Nov 2020 23:59'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 106'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAF)', Time: '2020-11-08T00:05:45', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '48f1f4a9-fe8d-4d52-848b-25796437d2d8'	System	08 Nov 2020 08:06:00
User entered 'No (N)'	System	08 Nov 2020 08:06:00



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

Have you been exposed to someone with 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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-11-08T00:05:49', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '48f1f4a9-fe8d-4d52-848b-25796437d2d8'	System	08 Nov 2020 08:06:00
User entered 'No (N)'	System	08 Nov 2020 08:06:00



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-11-08T00:05:58', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '48f1f4a9-fe8d-4d52-848b-25796437d2d8' User entered '08 Nov 2020 00:05:58'	System	08 Nov 2020 08:06:00
	System	08 Nov 2020 08:06:00



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '08 Nov 2020 00:01'	System	29 Jul 2020 00:20:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '12 Nov 2020 23:59'	System	29 Jul 2020 00:20:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered 'Day 113'	System	29 Jul 2020 00:20:56



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

[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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-11-15T00:55:23', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5d045206-2251-4315-9805-9d2fdd317406'	System	15 Nov 2020 08:55:42
User entered 'No (N)'	System	15 Nov 2020 08:55:42



US3262027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

Have you been exposed to someone with 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 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-11-15T00:55:27', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5d045206-2251-4315-9805-9d2fdd317406'	System	15 Nov 2020 08:55:42
User entered 'No (N)'	System	15 Nov 2020 08:55:42



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-11-15T00:55:40', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '5d045206-2251-4315-9805-9d2fdd317406' User entered '15 Nov 2020 00:55:40'	System	15 Nov 2020 08:55:42
	System	15 Nov 2020 08:55:42



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '15 Nov 2020 00:01'	System	29 Jul 2020 00:20:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:31:02
Data entry locked.	System	29 Jul 2020 00:20:56
User entered '19 Nov 2020 23:59'	System	29 Jul 2020 00:20:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-11-30T12:00:33', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2617163a-9ca9-46b1-9d0c-56c8be7a31d5'	System	30 Nov 2020 20:00:47
User entered 'No (N)'	System	30 Nov 2020 20:00:47



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-11-30T12:00:36', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2617163a-9ca9-46b1-9d0c-56c8be7a31d5'	System	30 Nov 2020 20:00:47
User entered 'No (N)'	System	30 Nov 2020 20:00:47



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-11-30T12:00:42', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '2617163a-9ca9-46b1-9d0c-56c8be7a31d5'	System	30 Nov 2020 20:00:47
User entered '30 Nov 2020 12:00:42'	System	30 Nov 2020 20:00:47



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:38:36



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-12-03T00:35:49', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'eb2f2e48-636d-44fd-b1a3-94904aaf1f94'	System	03 Dec 2020 08:36:06
User entered 'No (N)'	System	03 Dec 2020 08:36:06



US3262027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:15:03

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-12-03T00:35:54', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'eb2f2e48-636d-44fd-b1a3-94904aaf1f94'	System	03 Dec 2020 08:36:06
User entered 'No (N)'	System	03 Dec 2020 08:36:06



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-12-03T00:36:04', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'eb2f2e48-636d-44fd-b1a3-94904aaf1f94'	System	03 Dec 2020 08:36:06
User entered '03 Dec 2020 00:36:04'	System	03 Dec 2020 08:36:06



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-12-12T12:00:51', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'bb454d51-b834-4f4c-aae0-95965ea524a4'	System	12 Dec 2020 20:01:05
User entered 'No (N)'	System	12 Dec 2020 20:01:05



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-12-12T12:00:55', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'bb454d51-b834-4f4c-aae0-95965ea524a4'	System	12 Dec 2020 20:01:05
User entered 'No (N)'	System	12 Dec 2020 20:01:05



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-12-12T12:01:01', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'bb454d51-b834-4f4c-aae0-95965ea524a4' User entered '12 Dec 2020 12:01:01'	System	12 Dec 2020 20:01:05
	System	12 Dec 2020 20:01:05



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-12-20T18:00:09', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b39b42c2-9de5-4220-b4ee-d62f319b3e6a' User entered 'No (N)'	System	21 Dec 2020 02:00:27
	System	21 Dec 2020 02:00:27



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2020-12-20T18:00:13', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b39b42c2-9de5-4220-b4ee-d62f319b3e6a'	System	21 Dec 2020 02:00:27
User entered 'No (N)'	System	21 Dec 2020 02:00:27



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-12-20T18:00:21', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b39b42c2-9de5-4220-b4ee-d62f319b3e6a' User entered '20 Dec 2020 18:00:21'	System	21 Dec 2020 02:00:27
	System	21 Dec 2020 02:00:27



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-12-24T00:01:25', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9c4a4c35-a27e-456a-a07d-d8ea307fb7a9' User entered 'No (N)'	System	24 Dec 2020 08:02:09
	System	24 Dec 2020 08:02:09



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2020-12-24T00:01:55', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9c4a4c35-a27e-456a-a07d-d8ea307fb7a9'	System	24 Dec 2020 08:02:09
User entered 'No (N)'	System	24 Dec 2020 08:02:09



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2020-12-24T00:02:03', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9c4a4c35-a27e-456a-a07d-d8ea307fb7a9' User entered '24 Dec 2020 00:02:03'	System	24 Dec 2020 08:02:09
	System	24 Dec 2020 08:02:09



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-01-02T12:01:02', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '1a1c9674-682c-48ae-95b6-6cb44c2fb3c3'	System	02 Jan 2021 20:01:16
User entered 'No (N)'	System	02 Jan 2021 20:01:16



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-02T12:01:06', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '1a1c9674-682c-48ae-95b6-6cb44c2fb3c3'	System	02 Jan 2021 20:01:16
User entered 'No (N)'	System	02 Jan 2021 20:01:16



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-01-02T12:01:12', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '1a1c9674-682c-48ae-95b6-6cb44c2fb3c3' User entered '02 Jan 2021 12:01:12'	System	02 Jan 2021 20:01:16
	System	02 Jan 2021 20:01:16



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-10T19:12:05', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0d185c23-769f-4d37-9510-9099e57e9d77'	System	11 Jan 2021 03:12:36
User entered 'Yes (Y)'	System	11 Jan 2021 03:12:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-10T19:11:33', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0d185c23-769f-4d37-9510-9099e57e9d77'	System	11 Jan 2021 03:12:36
User entered 'No (N)'	System	11 Jan 2021 03:12:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-10T19:12:23', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0d185c23-769f-4d37-9510-9099e57e9d77'	System	11 Jan 2021 03:12:36
User entered 'No (N)'	System	11 Jan 2021 03:12:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-01-10T19:12:27', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0d185c23-769f-4d37-9510-9099e57e9d77'	System	11 Jan 2021 03:12:36
User entered 'No (N)'	System	11 Jan 2021 03:12:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-01-10T19:12:31', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0d185c23-769f-4d37-9510-9099e57e9d77'	System	11 Jan 2021 03:12:36
User entered '10 Jan 2021 19:12:31'	System	11 Jan 2021 03:12:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-14T00:53:34', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '84140949-6961-4de8-8447-69aa96183c4f'	System	14 Jan 2021 08:53:57
User entered 'No (N)'	System	14 Jan 2021 08:53:57



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-14T00:53:45', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '84140949-6961-4de8-8447-69aa96183c4f'	System	14 Jan 2021 08:53:57
User entered 'No (N)'	System	14 Jan 2021 08:53:57



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-14T00:53:55', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '84140949-6961-4de8-8447-69aa96183c4f' User entered '14 Jan 2021 00:53:55'	System	14 Jan 2021 08:53:57



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-21T04:18:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '375f8f8a-d045-4c23-bd26-8ef12362213d' User entered 'No (N)'	System	21 Jan 2021 12:18:14
	System	21 Jan 2021 12:18:14



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-21T04:18:04', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '375f8f8a-d045-4c23-bd26-8ef12362213d'	System	21 Jan 2021 12:18:14
User entered 'No (N)'	System	21 Jan 2021 12:18:14



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-01-21T04:18:12', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '375f8f8a-d045-4c23-bd26-8ef12362213d' User entered '21 Jan 2021 04:18:12'	System	21 Jan 2021 12:18:14
	System	21 Jan 2021 12:18:14



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-28T00:01:30', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '95b12954-79f1-4fa3-83f1-56190541a106'	System	28 Jan 2021 08:01:42
User entered 'No (N)'	System	28 Jan 2021 08:01:42



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-01-28T00:01:34', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '95b12954-79f1-4fa3-83f1-56190541a106'	System	28 Jan 2021 08:01:42
User entered 'No (N)'	System	28 Jan 2021 08:01:42



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-01-28T00:01:39', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '95b12954-79f1-4fa3-83f1-56190541a106'	System	28 Jan 2021 08:01:42
User entered '28 Jan 2021 00:01:39'	System	28 Jan 2021 08:01:42



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-02-07T17:59:45', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a9ab4fc0-7dde-4e9d-8f3d-10ef6a6e388a' User entered 'No (N)'	System	08 Feb 2021 01:59:58
	System	08 Feb 2021 01:59:58



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-02-07T17:59:49', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a9ab4fc0-7dde-4e9d-8f3d-10ef6a6e388a'	System	08 Feb 2021 01:59:58
User entered 'No (N)'	System	08 Feb 2021 01:59:58



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-02-07T17:59:54', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a9ab4fc0-7dde-4e9d-8f3d-10ef6a6e388a'	System	08 Feb 2021 01:59:58
User entered '07 Feb 2021 17:59:54'	System	08 Feb 2021 01:59:58



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-02-11T10:42:16', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0b5cc79b-6bfa-41fc-a652-5a2c3044f194'	System	11 Feb 2021 18:42:32
User entered 'No (N)'	System	11 Feb 2021 18:42:32



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-02-11T10:42:20', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0b5cc79b-6bfa-41fc-a652-5a2c3044f194'	System	11 Feb 2021 18:42:32
User entered 'No (N)'	System	11 Feb 2021 18:42:32



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-02-11T10:42:24', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '0b5cc79b-6bfa-41fc-a652-5a2c3044f194'	System	11 Feb 2021 18:42:32
User entered '11 Feb 2021 10:42:24'	System	11 Feb 2021 18:42:32



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-03-01T08:05:05-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fabb38bf-4ab5-4faf-925c-d359e4b65792'	System	01 Mar 2021 16:05:15
User entered 'No (N)'	System	01 Mar 2021 16:05:15



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-03-01T08:05:07-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fabb38bf-4ab5-4faf-925c-d359e4b65792'	System	01 Mar 2021 16:05:15
User entered 'No (N)'	System	01 Mar 2021 16:05:15



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-03-01T08:05:11-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'fabb38bf-4ab5-4faf-925c-d359e4b65792'	System	01 Mar 2021 16:05:15
User entered '01 Mar 2021 08:05:11'	System	01 Mar 2021 16:05:15



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-03-04T01:01:27-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a86ff1ba-9f4d-49fd-a69a-0a37c7cb719f'	System	11 Mar 2021 17:29:32
User entered 'No (N)'	System	11 Mar 2021 17:29:32



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-03-04T01:01:31-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a86ff1ba-9f4d-49fd-a69a-0a37c7cb719f'	System	11 Mar 2021 17:29:32
User entered 'No (N)'	System	11 Mar 2021 17:29:32



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-03-04T01:01:36-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'a86ff1ba-9f4d-49fd-a69a-0a37c7cb719f'	System	11 Mar 2021 17:29:32
User entered '04 Mar 2021 01:01:36'	System	11 Mar 2021 17:29:32



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-03-11T09:29:36-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '42c14407-9ec2-4cc8-a758-5e06f2fb512d'	System	11 Mar 2021 17:29:49
User entered 'No (N)'	System	11 Mar 2021 17:29:49



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-03-11T09:29:39-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '42c14407-9ec2-4cc8-a758-5e06f2fb512d'	System	11 Mar 2021 17:29:49
User entered 'No (N)'	System	11 Mar 2021 17:29:49



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-03-11T09:29:46-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '42c14407-9ec2-4cc8-a758-5e06f2fb512d' User entered '11 Mar 2021 09:29:46'	System	11 Mar 2021 17:29:49
	System	11 Mar 2021 17:29:49



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-03-18T00:24:35-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '61290b3e-e627-48c8-bf77-315cf8f12f4c'	System	18 Mar 2021 07:24:46
User entered 'No (N)'	System	18 Mar 2021 07:24:46



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-03-18T00:24:39-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '61290b3e-e627-48c8-bf77-315cf8f12f4c'	System	18 Mar 2021 07:24:46
User entered 'No (N)'	System	18 Mar 2021 07:24:46



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-03-18T00:24:43-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '61290b3e-e627-48c8-bf77-315cf8f12f4c' User entered '18 Mar 2021 00:24:43'	System	18 Mar 2021 07:24:46
	System	18 Mar 2021 07:24:46



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-03-27T12:00:23-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f9728e37-d3a5-49e1-8507-df3891836998'	System	27 Mar 2021 19:00:39
User entered 'No (N)'	System	27 Mar 2021 19:00:39



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-03-27T12:00:25-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f9728e37-d3a5-49e1-8507-df3891836998'	System	27 Mar 2021 19:00:39
User entered 'No (N)'	System	27 Mar 2021 19:00:39



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-03-27T12:00:29-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f9728e37-d3a5-49e1-8507-df3891836998'	System	27 Mar 2021 19:00:39
User entered '27 Mar 2021 12:00:29'	System	27 Mar 2021 19:00:39



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-04-01T00:45:42-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'bc1247ee-a1ef-4dd7-a156-ee3ba60d8b65'	System	01 Apr 2021 07:45:53
User entered 'No (N)'	System	01 Apr 2021 07:45:53



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-04-01T00:45:47-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'bc1247ee-a1ef-4dd7-a156-ee3ba60d8b65'	System	01 Apr 2021 07:45:53
User entered 'No (N)'	System	01 Apr 2021 07:45:53



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-04-01T00:45:51-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'bc1247ee-a1ef-4dd7-a156-ee3ba60d8b65'	System	01 Apr 2021 07:45:53
User entered '01 Apr 2021 00:45:51'	System	01 Apr 2021 07:45:53



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-04-10T12:01:09-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b9583fc2-d280-4e42-8b58-2bd2cb1dc6d8'	System	10 Apr 2021 19:01:25
User entered 'No (N)'	System	10 Apr 2021 19:01:25



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-04-10T12:01:15-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b9583fc2-d280-4e42-8b58-2bd2cb1dc6d8'	System	10 Apr 2021 19:01:25
User entered 'No (N)'	System	10 Apr 2021 19:01:25



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-04-10T12:01:20-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'b9583fc2-d280-4e42-8b58-2bd2cb1dc6d8'	System	10 Apr 2021 19:01:25
User entered '10 Apr 2021 12:01:20'	System	10 Apr 2021 19:01:25



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2021-04-18T17:59:20-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '8acfd927-c81b-4062-b820-a19e676b641b'	System	19 Apr 2021 01:00:18
User entered 'Yes (Y)'	System	19 Apr 2021 01:00:18



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2021-04-18T17:59:24-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '8acfd927-c81b-4062-b820-a19e676b641b'	System	19 Apr 2021 01:00:18
User entered 'No (N)'	System	19 Apr 2021 01:00:18



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-04-18T17:59:32-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '8acfd927-c81b-4062-b820-a19e676b641b'	System	19 Apr 2021 01:00:18
User entered 'No (N)'	System	19 Apr 2021 01:00:18



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFB)', Time: '2021-04-18T17:59:39-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '8acfd927-c81b-4062-b820-a19e676b641b'	System	19 Apr 2021 01:00:18
User entered 'Yes (Y)'	System	19 Apr 2021 01:00:18



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Please 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-04-18T17:59:50-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '8acfd927-c81b-4062-b820-a19e676b641b'	System	19 Apr 2021 01:00:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Apr 2021 01:00:18



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-04-18T18:00:01-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '8acfd927-c81b-4062-b820-a19e676b641b'	System	19 Apr 2021 01:00:18
User entered '18 Apr 2021 18:00:01'	System	19 Apr 2021 01:00:18



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-04-22T03:29:41-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f50451f5-c8dd-4e66-8d99-619143b31187'	System	22 Apr 2021 10:29:56
User entered 'No (N)'	System	22 Apr 2021 10:29:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-04-22T03:29:47-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f50451f5-c8dd-4e66-8d99-619143b31187'	System	22 Apr 2021 10:29:56
User entered 'No (N)'	System	22 Apr 2021 10:29:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFD)', Time: '2021-04-22T03:29:52-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: 'f50451f5-c8dd-4e66-8d99-619143b31187'	System	22 Apr 2021 10:29:56
User entered '22 Apr 2021 03:29:52'	System	22 Apr 2021 10:29:56



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-05-01T12:38:14-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9bedb417-56f1-4ff4-aca2-b824d982f7bf'	System	01 May 2021 19:38:30
User entered 'No (N)'	System	01 May 2021 19:38:30



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

Have you been exposed to someone with 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 (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-05-01T12:38:17-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9bedb417-56f1-4ff4-aca2-b824d982f7bf'	System	01 May 2021 19:38:30
User entered 'No (N)'	System	01 May 2021 19:38:30



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-05-01T12:38:27-07:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '9bedb417-56f1-4ff4-aca2-b824d982f7bf'	System	01 May 2021 19:38:30
User entered '01 May 2021 12:38:27'	System	01 May 2021 19:38:30



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 02:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 02:38:36



**US3262027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:15:03**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:38:36
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 02:38:36



US3262027

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:15:03

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 03:01:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-03-01T08:05:30-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '55c26e39-6e8d-4329-8efd-738075b6d5df'	System	01 Mar 2021 16:05:38
User entered 'No (N)'	System	01 Mar 2021 16:05:38



**US3262027**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:01:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DBEE0B4D-1C0E-4C9C-8250-EC37994EDAFC)', Time: '2021-03-01T08:05:34-08:00', User OID: 'PatientReportedOutcome (US3262027)', ODM File OID: '55c26e39-6e8d-4329-8efd-738075b6d5df' User entered '01 Mar 2021 08:05:34'	System	01 Mar 2021 16:05:38
	System	01 Mar 2021 16:05:38



**US3262027**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:31:14
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	17 Nov 2020 00:26:24



US3262027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:31:14
User entered '16 Nov 2020'	(b) (4) Daisy Langarica (b) (4)	17 Nov 2020 00:26:24
	(b) (4)	



**US3262027**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:31:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	17 Nov 2020 00:26:24



US3262027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:31:14
User entered empty.	(b) (4) Daisy Langarica (b) (4)	17 Nov 2020 00:26:24



US3262027

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:31:14
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	17 Nov 2020 00:26:32



**US3262027**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:15:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:23:25
User entered 'I'	System	17 Nov 2020 00:26:32



US3262027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langerica (b) (4)	17 Dec 2020 17:44:56
	(b) (4)	



US3262027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	17 Dec 2020 17:45:26
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	17 Dec 2020 17:45:26
User entered '15 Dec 2020' reason for change: Data Entry Error	Daisy Langarica (b) (4)	17 Dec 2020 17:45:26
	(b) (4)	
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	17 Dec 2020 17:44:56
User entered '25 Nov 2020'	Daisy Langarica (b) (4)	17 Dec 2020 17:44:56
	(b) (4)	



US3262027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[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 16:05:02
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:03:35
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:44:56



US3262027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	17 Dec 2020 17:44:56
	(b) (4)	



US3262027

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	17 Dec 2020 17:45:32
	(b) (4)	



US3262027

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User entered 'I'	System	17 Dec 2020 17:45:32



US3262027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 22:22:37



US3262027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 26AUG2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:43:23
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)	25 Feb 2021 14:32:26
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 'COMPLETED PER CRC AT THIS DAY' (Site from System).	Daisy Langarica (b) (4)	24 Feb 2021 21:45:08
User entered '11 Jan 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	24 Feb 2021 21:44:52
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	24 Feb 2021 21:44:28
User entered '15 Jan 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	24 Feb 2021 21:44:28
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 26AUG2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'this is a safety phone call no swab sample collected ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 00:42:18



US3262027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 26AUG2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 09:33:22
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)	04 Feb 2021 10:15:46
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 'Date confirmed as recorded.' (Site from System).	Alia Bober (b) (4) (b) (4)	03 Feb 2021 16:01:15
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	11 Jan 2021 22:22:37
User entered '11 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 22:22:37



US3262027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 22:22:37



US3262027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 22:22:37



US3262027

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 22:22:47



US3262027

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User entered 'I'	System	11 Jan 2021 22:22:47



US3262027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	24 Feb 2021 21:43:42
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	24 Feb 2021 21:00:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 21:00:04
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 18:30:06



US3262027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(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	24 Feb 2021 21:46:32
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	24 Feb 2021 21:46:32
User entered '15 Feb 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	24 Feb 2021 21:46:32
	(b) (4)	
User entered '29 Jan 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	24 Feb 2021 21:45:51
	(b) (4)	
User entered '18 Jan 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	24 Feb 2021 21:45:41
	(b) (4)	
User entered '27 Jan 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	24 Feb 2021 21:45:30
	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	24 Feb 2021 21:44:09
	(b) (4)	
User entered '23 Jan 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	24 Feb 2021 21:43:56
	(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	24 Feb 2021 21:43:42
User entered '27 Jan 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	24 Feb 2021 21:43:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:30:06



US3262027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4)	24 Feb 2021 21:43:42
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT	(b) (4), (b) (6)	24 Feb 2021 21:00:04
MADE)' reason for change: Data Entry Error		
User entered empty.		23 Feb 2021 18:30:06



US3262027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	24 Feb 2021 21:43:42
Please review and reconcile.' (Site from System).		
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	24 Feb 2021 21:00:04
Please review and reconcile.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:30:06



US3262027

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:30:10



**US3262027**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:15:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:05:02
User entered 'I'	System	23 Feb 2021 18:30:10



**US3262027**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	08 Mar 2021 20:58:48



US3262027

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '08 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	08 Mar 2021 20:58:48



US3262027

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4) (b) (4)	08 Mar 2021 20:58:48



**US3262027**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered 'VISIT4'	System	08 Mar 2021 20:58:48



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '08 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:58:23
	(b) (4)	



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '11:17'	(b) (4) Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered '08 Mar 2021 11:17'	System	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '98.1' F	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:58:23
	(b) (4)	



**US3262027**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered empty.	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '76'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:58:23



**US3262027**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered 'bpm'	System	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '14'	(b) (4) Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered 'breaths/min'	System	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '116'	(b) (4) Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered 'mmHg'	System	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '83'	(b) (4) Daisy Langarica (b) (4) (b) (4)	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered 'mmHg'	System	31 Mar 2021 21:58:23



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48



US3262027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48



US3262027

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	08 Mar 2021 20:58:52



US3262027

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered empty.	(b) (4) Daisy Langarica (b) (4) (b) (4)	08 Mar 2021 20:58:52



US3262027

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	08 Mar 2021 20:59:07



US3262027

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '08 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	08 Mar 2021 20:59:07
	(b) (4)	



US3262027

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '11:25'	(b) (4) Daisy Langarica (b) (4)	08 Mar 2021 20:59:07



**US3262027**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:15:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered '08 Mar 2021 11:25'	System	08 Mar 2021 20:59:07



US3262027

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	08 Mar 2021 20:59:16



US3262027

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered 'I'	System	08 Mar 2021 20:59:16



US3262027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	19 Apr 2021 18:03:00
	(b) (4)	



US3262027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered '19 Apr 2021'	Daisy Langarica (b) (4)	19 Apr 2021 18:03:00
	(b) (4)	



**US3262027**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:15:03**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4)	19 Apr 2021 18:03:00
	(b) (4)	



US3262027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:15:03

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 18:03:00
	(b) (4)	



US3262027

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:15:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	19 Apr 2021 18:03:05
	(b) (4)	



**US3262027**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:15:03**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 18:03:05



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:15:03

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:08
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "correct as is there was no unscheduled visit conducted"; however, per PPD portal, swab sample was collected at Unscheduled visit on 26 AUG 2020. Kindly confirm in site response, sample name that was collected for this subject at Unscheduled visit on 26 AUG 2020, else the subject ID for which swab sample was collected.' (Site from DM).		01 Mar 2021 11:40:22
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "correct as is there was no unscheduled visit conducted"; however, per PPD portal, swab sample was collected at Unscheduled visit on 26 AUG 2020. Kindly confirm in site response, sample name that was collected for this subject at Unscheduled visit on 26 AUG 2020, else the subject ID for which swab sample was collected.' answered with 'Not unscheduled visit "Illness D1" visit conducted 26AUG2020' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 15:58:33
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "correct as is there was no unscheduled visit conducted"; however, per PPD portal, swab sample was collected at Unscheduled visit on 26 AUG 2020. Kindly confirm in site response, sample name that was collected for this subject at Unscheduled visit on 26 AUG 2020, else the subject ID for which swab sample was collected.' (Site from DM).		30 Dec 2020 06:37:27
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-AUG-2020 is reported under Unscheduled visit in PPD portal; however, the corresponding swab sample is missing in EDC for date 26-AUG-2020. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.  ' (Site from DM).		18 Dec 2020 04:36:27



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:15:03

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-AUG-2020 is reported under Unscheduled visit in PPD portal; however, the corresponding swab sample is missing in EDC for date 26-AUG-2020. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.  ' answered with 'CORRECT AS IS THERE WAS NO UNSCHEDULED VISIT CONDUCTED ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:33:43
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-AUG-2020 is reported under Unscheduled visit in PPD portal; however, the corresponding swab sample is missing in EDC for date 26-AUG-2020. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.	(b) (4), (b) (6)	02 Dec 2020 05:51:05
' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab Sample reported under Illness visit is dated 26Aug2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' canceled (Site from DM).		02 Dec 2020 05:50:13
User opened query 'Per GCL Lab Reconciliation: Swab Sample reported under Illness visit is dated 26Aug2020 in PPD Central lab. Please reconcile and update if applicable. Else clarify, thank you' (Site from DM).		25 Oct 2020 22:52:59
User entered '26 Aug 2020'		30 Aug 2020 21:41:54



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:15:03

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:08
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As Per response "YES IT WAS", however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 26 AUG 2020, please verify and update the data as needed, else clarify. Thank you.' (Site from DM).		26 Feb 2021 08:07:02
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As Per response "YES IT WAS", however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 26 AUG 2020, please verify and update the data as needed, else clarify. Thank you.' answered with 'Illness visit date recorded 26 Aug 2020' (Site from DM).	Alia Bober (b) (4) (b) (4)	24 Feb 2021 16:04:52
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As Per response "YES IT WAS", however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 26 AUG 2020, please verify and update the data as needed, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:10:31
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		18 Dec 2020 07:10:31
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'YES IT WAS ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:33:57

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:15:03

[Time of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). User entered '11:47'	(b) (4), (b) (6)	30 Oct 2020 00:10:03
		30 Aug 2020 21:41:54



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:15:03

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:19
User entered '26 Aug 2020 11:47'	System	30 Aug 2020 21:41:54



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:15:03

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:08
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	30 Aug 2020 21:41:54



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:15:03

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:19
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:08
User closed query 'Please verify and enter the following missing pages: Symptom log, Diagnostic test page, Illness Visit Day 1, Saliva collected until negative result received.' (Site from CRA).		12 Mar 2021 21:32:20
Query 'Please verify and enter the following missing pages: Symptom log, Diagnostic test page, Illness Visit Day 1, Saliva collected until negative result received.' answered with 'pending reports from VIRACOR - YOU can requery we still have not received reports all state pending its almost been a yr (b) (6) was aware of issue ' (Site from CRA).	Daisy Langarica (b) (4) (b) (4)	26 Feb 2021 19:00:31
User opened query 'Please verify and enter the following missing pages: Symptom log, Diagnostic test page, Illness Visit Day 1, Saliva collected until negative result received.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 23:52:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 21:41:54



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:16
User entered '26 Aug 2020'	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:43:10



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:16
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:43:10



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:51:36
User closed query 'Per CDM: Per sponsor review, please confirm subject tested positive for SARS-CoV-2. If confirmed, please complete Symptom Log and Severity Assessment. ' (Site from DM).		06 Apr 2021 10:01:21
Query 'Per CDM: Per sponsor review, please confirm subject tested positive for SARS-CoV-2. If confirmed, please complete Symptom Log and Severity Assessment. ' answered with 'negative results finally received today thank you ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	05 Apr 2021 23:52:49
DataPoint Un-verified.	Daisy Langarica (b) (4) (b) (4)	05 Apr 2021 23:52:29
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	05 Apr 2021 23:52:29
User opened query 'Per CDM: Per sponsor review, please confirm subject tested positive for SARS-CoV-2. If confirmed, please complete Symptom Log and Severity Assessment. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 17:21:58
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:29:16
User closed query 'Per CDM: Please indicate Yes or No as per CCG, once data is available' (Site from DM).		25 Feb 2021 14:13:07
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		25 Feb 2021 14:13:04
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Yes positive test.' (Site from System).	Alia Bober (b) (4) (b) (4)	24 Feb 2021 16:01:25



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Query 'Per CDM: Please indicate Yes or No as per CCG, once data is available' answered with 'Yes' (Site from DM).	Alia Bober (b) (4) (b) (4)	24 Feb 2021 16:01:04
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	22 Feb 2021 16:06:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 16:06:18
User closed query 'Data is required. Please complete.' (Site from System).		21 Dec 2020 16:14:21
User opened query 'Per CDM: Please indicate Yes or No as per CCG, once data is available' (Site from DM).		21 Dec 2020 16:14:18
Query 'Data is required. Please complete.' answered with 'NO RESULTS YET SENT TO SITE SEE CORRESPONDENCE IN CHART ' (Site from System).	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:43:36
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 17:43:10
User entered empty.	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:43:10



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26AUG2020 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).		21 Feb 2021 10:14:59
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26AUG2020 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		24 Dec 2020 07:16:48
User entered '26 Aug 2020'	Daisy Langerica (b) (4) (b) (4)	17 Dec 2020 17:43:10



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 26AUG2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Apr 2021 13:52:17 01 Apr 2021 22:20:37
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 26AUG2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'It was a data entry error as a swab was done, not a saliva test.' (Site from DM). DataPoint Un-verified.	Atoya Adams (b) (4) (b) (4)	24 Mar 2021 17:14:33
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Atoya Adams (b) (4) Atoya Adams (b) (4)	24 Mar 2021 17:13:56 24 Mar 2021 17:13:56
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 26AUG2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 05:30:29 18 Mar 2021 19:29:16
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:44:34
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:43:10



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:16
User entered empty.	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:43:10



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:16
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:43:10



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:16
User entered empty.	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:43:10



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:29:16
User entered empty.	Daisy Langarica (b) (4) (b) (4)	17 Dec 2020 17:43:10



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:15:03

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:13
User entered '0'	System	05 Apr 2021 23:52:29
User entered '1'	System	22 Feb 2021 16:06:18



US3262027

Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:15:03

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:32:47
Data hard unlocked.		03 May 2021 21:18:14
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:54:40
Data hard locked.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:47:52
DataPoint activated with code reason code Data required.		30 Apr 2021 17:47:46
DataPoint inactivated with code reason code Data not required.		30 Apr 2021 17:43:01
Signature has been broken.		30 Apr 2021 17:43:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:51:56
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	25 Mar 2021 16:53:07



US3262027

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:15:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered empty.		23 Feb 2021 18:50:54



US3262027

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:15:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:15:03**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered 'NA (COVID-19 Negative) (NA)'		23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 16:15:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered empty.		23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered 'NA (COVID-19 Negative) (NA)'		23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered empty.		23 Feb 2021 18:50:54



US3262027

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:15:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered 'NA (COVID-19 Negative) (NA)'		23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered empty.		23 Feb 2021 18:50:54



US3262027

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:15:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:15:03**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered 'NA (COVID-19 Negative) (NA)'		23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 16:15:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered empty.		23 Feb 2021 18:50:54



US3262027

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:15:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered 'NA (COVID-19 Negative) (NA)'		23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered empty.		23 Feb 2021 18:50:54



US3262027

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:15:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered 'NA (COVID-19 Negative) (NA)'		23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:13
User entered empty.		23 Feb 2021 18:50:54



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:15:55
User entered 'Yes (Y)'		22 Feb 2021 15:59:13



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:15:55
User entered '26 Aug 2020'		22 Feb 2021 15:59:13



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:15:55
User entered 'Clinic (Clinic)'		22 Feb 2021 15:59:13



US3262027

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User entered 'SICKD1'	System	22 Feb 2021 15:59:13



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered 'Yes (Y)'		22 Feb 2021 16:00:06



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered '26 Aug 2020'		22 Feb 2021 16:00:06



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered '11:58'		22 Feb 2021 16:00:06



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User entered '26 Aug 2020 11:58'	System	22 Feb 2021 16:00:06



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered missing code ND - Not Done.		22 Feb 2021 16:00:06
DataPoint set to visible.	System	22 Feb 2021 15:59:13



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered missing code ND - Not Done.		22 Feb 2021 16:00:06
DataPoint set to visible.	System	22 Feb 2021 15:59:13



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered '98.3' F		22 Feb 2021 16:00:06



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered 'Oral (Oral)'		22 Feb 2021 16:00:06



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered empty.		22 Feb 2021 16:00:06



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered '87'		22 Feb 2021 16:00:06



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User entered 'bpm'	System	22 Feb 2021 16:00:06



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered '16'		22 Feb 2021 16:00:06



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User entered 'breaths/min'	System	22 Feb 2021 16:00:06



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered '114'		22 Feb 2021 16:00:06



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User entered 'mmHg'	System	22 Feb 2021 16:00:06



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:09
User entered '68'		22 Feb 2021 16:00:06



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User entered 'mmHg'	System	22 Feb 2021 16:00:06



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56



US3262027

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56



US3262027

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:45
User entered 'Yes (Y)'		22 Feb 2021 16:00:26



**US3262027**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:15:03**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:19:45
User entered '26 Aug 2020'		22 Feb 2021 16:00:26



US3262027

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:15:03

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:24:54
User entered 'Yes (Y)'		22 Feb 2021 16:00:42



US3262027

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:15:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:24:54
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please confirm the date of SARS-CoV-2 serum sample collection date as reported date (22 AUG 2020) is discrepant with visit date (26 AUG 2020) of illness visit' (Site from DM).		01 Mar 2021 11:48:56
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please confirm the date of SARS-CoV-2 serum sample collection date as reported date (22 AUG 2020) is discrepant with visit date (26 AUG 2020) of illness visit' answered with 'updated thank you ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	26 Feb 2021 18:58:46
User entered '26 Aug 2020' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	26 Feb 2021 18:58:36
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Please confirm the date of SARS-CoV-2 serum sample collection date as reported date (22 AUG 2020) is discrepant with visit date (26 AUG 2020) of illness visit' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 08:09:02
User entered '22 Aug 2020'		22 Feb 2021 16:00:42



**US3262027**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:28:08
User entered 'No (N)'		23 Feb 2021 18:50:14



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:28:08
User entered empty.		23 Feb 2021 18:50:14



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[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 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:28:08
User entered empty.		23 Feb 2021 18:50:14



**US3262027**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	23 Feb 2021 18:50:14



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered 'No (N)'		23 Feb 2021 18:50:29



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered empty.		23 Feb 2021 18:50:29



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered empty.		23 Feb 2021 18:50:29



**US3262027**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:50:29



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered empty.		23 Feb 2021 18:50:29



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered empty.		23 Feb 2021 18:50:29



**US3262027**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered empty.		23 Feb 2021 18:50:29



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered empty.		23 Feb 2021 18:50:29



**US3262027**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:50:29



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered empty.		23 Feb 2021 18:50:29



**US3262027**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:50:29



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered empty.		23 Feb 2021 18:50:29



**US3262027**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:50:29



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:15:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:23
User entered empty.		23 Feb 2021 18:50:29



**US3262027**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:15:03**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 18:50:29



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:40
User entered 'No (N)'		23 Feb 2021 18:50:34



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:15:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:40
User entered empty.		23 Feb 2021 18:50:34



US3262027

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 16:15:03**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:54
User entered 'NA (COVID-19 Negative) (NA)'		23 Feb 2021 18:50:41



US3262027

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:15:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:54
User entered empty.		23 Feb 2021 18:50:41



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:08:19



US3262027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:08:19



US3262027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:15:03

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Feb 2021 17:08:19



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:15:03**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 17:08:19



US3262027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:15:03

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:10:51



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:15:03**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:03:52



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:15:03**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:10:51



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:15:03**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
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 02:03:52



US3262027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:15:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:10:51



US3262027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:15:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	04 Feb 2021 17:10:51



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:15:03**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:10:51



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:15:03**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:10:51



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:15:03**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:10:51



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:15:03**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered empty.	System	04 Feb 2021 17:10:51



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:15:03**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:48
User entered empty.	System	04 Feb 2021 17:10:51



US3262027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:45
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 17:11:12



US3262027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:15:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:45
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:11:12



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:15:03**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:45
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '9:01'	(b) (4), (b) (6)	04 Feb 2021 17:11:12



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:15:03**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:45
User entered '4 Feb 2021 9:01'	System	04 Feb 2021 17:11:12



US3262027

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:15:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:45
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:11:26



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:15:03**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:45
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:11:26



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:15:03**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:45
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
User entered '8:59'	(b) (4), (b) (6)	04 Feb 2021 17:11:26



**US3262027**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:15:03**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:19:45
User entered '4 Feb 2021 8:59'	System	04 Feb 2021 17:11:26



US3262027

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:15:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:53:45
User signature succeeded.	Atoya Adams (b) (4)	19 Apr 2021 19:11:16
Signature has been broken.	(b) (4) Daisy Langarica (b) (4)	19 Apr 2021 16:05:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Daisy Langarica (b) (4)	19 Apr 2021 16:05:57
User signature succeeded.	(b) (4) Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:29:10



**US3262027**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:15:03**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'USA-US069-2021-mRNA-1273-P301000006'	(b) (4) System	20 Apr 2021 18:28:24
User entered 'New' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Apr 2021 18:28:24
User entered empty.		20 Apr 2021 18:28:00



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 16:12:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 16:12:10
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 16:08:14
User entered 'Pneumonia'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	19 Apr 2021 17:52:48
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:53:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	19 Apr 2021 16:53:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:07:10
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:53:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	19 Apr 2021 16:53:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:07:10
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:53:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered '08 Apr 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	19 Apr 2021 16:53:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:07:10
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



**US3262027**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



**US3262027**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:15:03**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:07:10



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:53:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	19 Apr 2021 16:53:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:07:10
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	19 Apr 2021 16:53:59
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered '11 Apr 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	19 Apr 2021 16:53:59
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	19 Apr 2021 16:07:10
User entered empty.	System	19 Apr 2021 16:07:10
	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



**US3262027**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:15:03**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



**US3262027**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:15:03**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 16:07:10



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:53:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	19 Apr 2021 16:53:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:07:10
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:27:54
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' answered with 'updated ' (Site from Safety).	Daisy Langarica (b) (4) (b) (4)	19 Apr 2021 16:54:32
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Apr 2021 16:53:59
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:35:33
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Apr 2021 16:07:10
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	19 Apr 2021 16:07:10



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



US3262027

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	19 Apr 2021 16:53:59
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered '1' reason for change: Data Entry Error	Daisy Langarica (b) (4)	19 Apr 2021 16:53:59
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	19 Apr 2021 16:07:10
User entered '0'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '08 Apr 2021'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '11 Apr 2021'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4) System	20 Apr 2021 15:35:08
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		20 Apr 2021 15:35:08
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	20 Apr 2021 15:35:08
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Apr 2021 16:07:10
User entered 'Unknown (UNK)'	Daisy Langarica (b) (4) (b) (4)	19 Apr 2021 16:07:10



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:27:51
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated ' (Site from Safety).	Daisy Langarica (b) (4) (b) (4)	19 Apr 2021 16:54:44
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:53:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	19 Apr 2021 16:53:59
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:35:03
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:07:10
User entered empty.	Daisy Langarica (b) (4) (b) (4)	19 Apr 2021 16:07:10



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:27:48
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated ' (Site from Safety).	Daisy Langarica (b) (4) (b) (4)	19 Apr 2021 16:54:48
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:53:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	19 Apr 2021 16:53:59
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:35:11
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:07:10
User entered empty.	Daisy Langarica (b) (4) (b) (4)	19 Apr 2021 16:07:10



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	27 Apr 2021 18:14:23
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:53:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 16:53:59
User entered 'None (NONE)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	19 Apr 2021 16:53:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 16:07:10
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

None

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'I'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Daisy Langarica (b) (4)	20 Apr 2021 15:35:56
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:15:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	19 Apr 2021 16:07:10
	(b) (4)	



**US3262027**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:07:10



**US3262027**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 17:52:48
User entered '0'	System	19 Apr 2021 16:53:59



**US3262027**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 16:07:10



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Medication errors and other product use errors and issues, HLT: Product administration errors and issues, PT: Inappropriate schedule of product administration, LLT: Inappropriate schedule of product administration - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 16:20:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 16:20:37
Data point term sent to Coder	System	20 Apr 2021 16:20:06
User entered 'INVESTIGATIONAL PRODUCT DELAY'	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'No (N)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'No (N)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'No (N)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	20 Apr 2021 16:19:28
User entered '01 Sep 2020' reason for change: Data Entry Error	System	20 Apr 2021 16:19:28
User opened query 'Future date has been entered. Please correct.' (Site from System).	Daisy Langarica (b) (4)	20 Apr 2021 16:19:28
User entered '01 Sep 2021'	(b) (4)	20 Apr 2021 16:19:15
DataPoint activated with code reason code Data required.	System	20 Apr 2021 16:19:15
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	20 Apr 2021 15:29:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered empty.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User entered empty.	System	20 Apr 2021 16:19:15
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'No (N)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	20 Apr 2021 16:19:28
User entered '21 Sep 2020' reason for change: Data Entry Error	System	20 Apr 2021 16:19:28
User opened query 'Future date has been entered. Please correct.' (Site from System).	Daisy Langarica (b) (4)	20 Apr 2021 16:19:28
User entered '21 Sep 2021'	(b) (4)	20 Apr 2021 16:19:15
DataPoint activated with code reason code Data required.	System	20 Apr 2021 16:19:15
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	20 Apr 2021 15:29:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered empty.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



US3262027

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User entered empty.	System	20 Apr 2021 16:19:15
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55



US3262027

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
DataPoint activated with code reason code Data required.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



US3262027

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'No (N)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered '0'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered '0'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered '0'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered empty.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered empty.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered empty.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered empty.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered '0'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered '0'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered '0'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'None (NONE)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'I'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered '0'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered '0'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
DataPoint activated with code reason code Data required.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered empty.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User entered empty.	(b) (4)	
	Daisy Langarica (b) (4)	20 Apr 2021 16:19:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User entered '0'	System	20 Apr 2021 16:19:15
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
User entered '0'	System	20 Apr 2021 16:19:15
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:15:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:13:17
DataPoint activated with code reason code Data required.	Daisy Langarica (b) (4)	20 Apr 2021 16:18:13
DataPoint inactivated with code reason code Data not required.	Daisy Langarica (b) (4)	20 Apr 2021 15:29:55



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:15:03

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:53:45
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User closed query 'Per CDM: Response noted however, there currently is no corresponding Conmed recorded for Diary Dose 1 Day 1, HEADACHE, Dose 2 Day 1, and 2, PAIN AT INJECTION SITE = Any use of prescription pain reliever or prevents daily activity? Please reconcile and update to record the medication given as appropriate or, provide log line number ensuring indication/dates correspond with these records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 13:57:49
Query 'Per CDM: Response noted however, there currently is no corresponding Conmed recorded for Diary Dose 1 Day 1, HEADACHE, Dose 2 Day 1, and 2, PAIN AT INJECTION SITE = Any use of prescription pain reliever or prevents daily activity? Please reconcile and update to record the medication given as appropriate or, provide log line number ensuring indication/dates correspond with these records.' answered with 'CON MED 8 AND 9' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 18:33:25
User opened query 'Per CDM: Response noted however, there currently is no corresponding Conmed recorded for Diary Dose 1 Day 1, HEADACHE, Dose 2 Day 1, and 2, PAIN AT INJECTION SITE = Any use of prescription pain reliever or prevents daily activity? Please reconcile and update to record the medication given as appropriate or, provide log line number ensuring indication/dates correspond with these records.' (Site from DM).		23 Feb 2021 11:42:26
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache, Dose 2 Day 1, and 2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).		23 Feb 2021 11:42:26



Were any prior/concomitant medications and/or vaccinations taken?

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:15:03

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.  ' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	05 Oct 2020 07:15:21
	Daisy Langarica (b) (4) (b) (4)	02 Aug 2020 22:07:55



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Dec 2020 15:24:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:24:56
Data point term sent to Coder	System	04 Dec 2020 15:24:09
User entered 'Escitalopram'	Alia Bober (b) (4) (b) (4)	04 Dec 2020 15:23:54



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Depression'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '20'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'once daily (QD)'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'UN UNK 2018'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:15:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:23:54
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:23:54



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:23:54



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:23:54



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Dec 2020 15:28:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:28:04
Data point term sent to Coder	System	04 Dec 2020 15:27:11
User entered 'Baclofen'	Alia Bober (b) (4) (b) (4)	04 Dec 2020 15:26:46



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:15:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Muscle spasms'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '10'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'once daily (QD)'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:15:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'UN UNK 2014'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:15:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:26:46
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:26:46



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:26:46



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:26:46



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE, PRODUCTSYNONYM: MORPHINE [MORPHINE SULFATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Dec 2020 14:18:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:18:44
Data point term sent to Coder	System	04 Dec 2020 15:28:11
User entered 'Morphine Sulfate-ER'	Alia Bober (b) (4) (b) (4)	04 Dec 2020 15:28:04



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Chronic back pain'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '15'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'twice daily (BID)'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'UN UNK 2014'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:15:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:28:04
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Dec 2020 15:28:04



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:28:04



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:28:04



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE, PRODUCTSYNONYM: MORPHINE [MORPHINE SULFATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Dec 2020 14:19:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:19:44
Data point term sent to Coder	System	04 Dec 2020 15:30:12
User entered 'Morphine sulfate - IR'	Alia Bober (b) (4) (b) (4)	04 Dec 2020 15:29:17



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Chronic back pain'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '15'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'three times daily (TID)'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:15:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Un UNK 2014'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:29:17
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	04 Dec 2020 15:29:17



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:29:17



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:29:17



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Dec 2020 15:33:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:33:05
Data point term sent to Coder	System	04 Dec 2020 15:32:13
User entered 'Flurosemide'	Alia Bober (b) (4) (b) (4)	04 Dec 2020 15:31:24



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Lower extremity edema'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '80'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'once daily (QD)'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'UN Apr 2020'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:15:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:31:24
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:31:24



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:31:24



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:31:24



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Dec 2020 20:42:56
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:42:56
Data point term sent to Coder	System	04 Dec 2020 15:38:18
User entered 'Potassium chloride'	Alia Bober (b) (4) (b) (4)	04 Dec 2020 15:38:01



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4)	24 Feb 2021 13:57:00
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Per Query Resolution		
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		
User entered 'No (N)'		
	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Nutritional Support'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '10'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Other (OTHER)'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Multiequivalents'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'once daily (QD)'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'UN Apr 2020'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:15:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:38:01
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:38:01



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:38:01



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:38:01



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR SYSTEMIC USE, ATC: ANTIFUNGALS FOR SYSTEMIC USE, PRODUCT: TERBINAFINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Dec 2020 23:06:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 23:06:43
Data point term sent to Coder	System	04 Dec 2020 15:40:20
User entered 'Terbinafiine'	Alia Bober (b) (4) (b) (4)	04 Dec 2020 15:40:04



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Onychomycosis of toes'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '250'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:15:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'once daily (QD)'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'UN Apr 2020'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:40:04
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:40:04



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:40:04



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:40:04



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Dec 2020 15:47:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:47:59
Data point term sent to Coder	System	04 Dec 2020 15:47:24
User entered 'Ibuprofen'	Alia Bober (b) (4) (b) (4)	04 Dec 2020 15:46:29



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:15:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Headache'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '200'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'as needed (PRN)'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:15:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '22 Aug 2020'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:15:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:46:29
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 15:46:29



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 15:46:29



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 15:46:29



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Dec 2020 21:43:48
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 21:43:48
Data point term sent to Coder	System	04 Dec 2020 15:51:27
User entered 'Ibuprofen'	Alia Bober (b) (4) (b) (4)	04 Dec 2020 15:50:36



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:15:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Muscle body aches'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '200'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'mg (mg)'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:15:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'once daily (QD)'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:15:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Oral (ORAL)'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:15:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '22 Aug 2020'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered '0'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:15:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered empty.	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
	(b) (4)	
User entered 'Yes (Y)'	Alia Bober (b) (4)	04 Dec 2020 15:50:36
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:50:36



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:50:36



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:50:36



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 15:43:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 15:43:35
Data point term sent to Coder	System	20 Apr 2021 15:42:28
User entered 'ceftriaxone'	Daisy Langarica (b) (4) (b) (4)	20 Apr 2021 15:41:34



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'PNEUMONIA'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '1'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'g (g)'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:15:03**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'other (OTHER)'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Q 24 HRS'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '08 Apr 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	20 Apr 2021 15:46:22
	(b) (4)	
User entered '10 Apr 2021'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '10 Apr 2021'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:15:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	20 Apr 2021 15:41:34
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 15:41:34



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 15:41:34



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 15:41:34



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:15:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 15:49:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 15:49:35
Data point term sent to Coder	System	20 Apr 2021 15:48:35
User entered 'AZITHROMYCIN'	Daisy Langarica (b) (4) (b) (4)	20 Apr 2021 15:47:41



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'PNEUMONIA'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:15:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '250'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'mL (mL)'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:15:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'other (OTHER)'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Q 24 HOURS'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:15:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '08 Apr 2021'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:15:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '10 Apr 2021'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



US3262027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:15:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'No (N)'	Daisy Langarica (b) (4)	20 Apr 2021 15:47:41
	(b) (4)	



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 15:47:41



US3262027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 15:47:41



**US3262027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:15:03**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 15:47:41



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:15:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:53:45
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
Signature has been broken.	Daisy Langarica (b) (4)	20 Apr 2021 15:47:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Daisy Langarica (b) (4)	20 Apr 2021 15:47:50
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 19:53:27
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:53
DataPoint Verified.		01 Apr 2021 22:12:50
User entered 'No (N)'	Daisy Langarica (b) (4)	02 Aug 2020 22:08:01



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:15:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '07 Apr 2021'	Daisy Langarica (b) (4)	20 Apr 2021 15:51:52
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:15:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'XR CHEST 1 VIEW FRONTAL - THE CARDIO MEDIASTINAL DEMONSTRATES NO ACUTE ABNORMALITIES LOW LUNG VOLUMES ARE PRESENT. RT UPPER AND LOWER LOBE INFILTRATES & OR ATELECTATIC CHANGES PRESENT NO EFFUSION OR'	Daisy Langarica (b) (4) (b) (4)	20 Apr 2021 15:51:52



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Adverse Event (AE)'	Daisy Langarica (b) (4)	20 Apr 2021 15:51:52
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:15:03

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	20 Apr 2021 15:51:52
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:15:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '07 Apr 2021'	Daisy Langarica (b) (4)	20 Apr 2021 15:53:52
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:15:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'CULTURE BLOOD ARD - NO GROWTH AT FOUR DAYS VERIFIED - 12 APR 2021'	Daisy Langarica (b) (4)	20 Apr 2021 15:53:52
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Adverse Event (AE)'	Daisy Langarica (b) (4)	20 Apr 2021 15:53:52
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:15:03

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	20 Apr 2021 15:53:52
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:15:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '07 Apr 2021'	Daisy Langarica (b) (4)	20 Apr 2021 15:55:13
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:15:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'SARS COV-2 LMC - NEGATIVE'	Daisy Langarica (b) (4)	20 Apr 2021 15:55:13
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Adverse Event (AE)'	Daisy Langarica (b) (4)	20 Apr 2021 15:55:13
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:15:03

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	20 Apr 2021 15:55:13
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:15:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered '07 Apr 2021'	Daisy Langarica (b) (4)	20 Apr 2021 15:59:31
	(b) (4)	



US3262027

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 16:15:03**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'CT ANGIO CHEST/W CONTRAST INC W/O IMAGES'	Daisy Langarica (b) (4)	20 Apr 2021 15:59:31
	(b) (4)	



US3262027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:15:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Daisy Langarica (b) (4)	20 Apr 2021 15:59:31
	(b) (4)	



US3262027

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 16:15:03**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:20
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	20 Apr 2021 15:59:31
	(b) (4)	



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'USA-US069-2021-MRNA-1273-P301000006'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'Yes (Y)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'Yes (Y)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



US3262027

Folder: SAE USA-US069-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'Atoya'	System	20 Apr 2021 18:28:24



US3262027

Folder: SAE USA-US069-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'Adams'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered '2121 E. Flamingo Road'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'las vegas'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'NV'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered '89119'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'US'	System	20 Apr 2021 18:28:33



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 18:28:33



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'USA-US069-2021-MRNA-1273-P301000006'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'Yes (Y)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'Yes (Y)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'No (N)'	System	20 Apr 2021 18:28:24



US3262027

Folder: SAE USA-US069-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:15:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'Atoya'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'Adams'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered '2121 E. Flamingo Road'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'las vegas'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'NV'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered '89119'	System	20 Apr 2021 18:28:24



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
Reviewed for Safety.		20 Apr 2021 18:28:37
User entered 'US'	System	20 Apr 2021 18:28:33



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:15:03**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 18:28:33



**US3262027**

**Folder: SAE USA-US069-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:15:03**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:07:44
User entered '20/Apr/2021 14:28'	System	20 Apr 2021 18:28:33



US3262027

Folder: SAE USA-US069-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:15:03

**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)	28 Apr 2021 16:03:35
DataPoint Verified.	(b) (4)	21 Apr 2021 16:07:44
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 18:28:37
User entered 'I'		20 Apr 2021 18:28:33