

US3042309 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:59:37

All time stamps listed in this document are displayed in GMT

**US3042309**

**Form: Participant Creation**

**Data signed: (b) (4) 28 Apr 2021 22:00:02**

**Generated On: 09 Jun 2021 14:59:37**

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[Participant ID](#)

US3042309

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

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US3042309

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Date of Birth (MMM yyyy)	(b) (6) 1981
Age	39
Age Units	YEARS
Age (Derived)	39
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) 28 Apr 2021 22:00:05

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 22:00:05

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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) 28 Apr 2021 22:00:05

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 22:00:05

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Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 22:00:05

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Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Condition	NARCOTIC ABUSE
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN JAN 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Condition	LOW TESTOSTERONE
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:37 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 13:37
Height ( <i>xxx.x</i> )	190.5 cm
Weight ( <i>xxx.x</i> )	139.4 kg
BMI ( <i>xxx.x</i> )	38.41252 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) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 22:00:05

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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**

WORKS IN HR DEPARTMENT  
FOR AMAZON; SEES  
COWORKERS ON A DAILY  
BASIS

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

**No Risk Identified** False

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PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 22:00:05

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<b>Resides in Nursing Home or Assisted Living Facility</b>	False
<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)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 107428

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Data signed: (b) (4) 28 Apr 2021 22:00:05**

**Generated On: 09 Jun 2021 14:59:37**

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) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

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)	22 AUG 2020
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 13:37
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

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)	22 AUG 2020
Time of assessment (00:00-23:59)	14:57 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 14:57
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:00:05

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

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) 22 AUG 2020

What was the treatment time? (00:00-23:59) 14:17 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 14:17

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) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 AUG 2020
Collection time (00:00-23:59)	14:03 (24 HR)
Collection date and time (derived)	22 AUG 2020 14:03

US3042309

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:50	22 AUG 2020 13:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 22 AUG 2020 14:53

PC Open Date & Time 22 AUG 2020 14:37

PC Close Date & Time 22 AUG 2020 17:07

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**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 97.8 °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):

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

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

PC Time Stamp 23 AUG 2020 00:10

PC Open Date & Time 22 AUG 2020 18:02

PC Close Date & Time 23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

23 AUG 2020 23:33

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 00:47

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 15:31

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**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

97.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

27 AUG 2020 07:57

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**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

97.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

27 AUG 2020 14:55

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**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

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 AUG 2020 00:43

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 8

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:00

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**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

22 AUG 2020 14:53

PC Open Date & Time

22 AUG 2020 14:37

PC Close Date & Time

22 AUG 2020 17:07

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**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

23 AUG 2020 00:11

PC Open Date & Time

22 AUG 2020 18:02

PC Close Date & Time

23 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**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

23 AUG 2020 23:33

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**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

25 AUG 2020 00:48

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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

25 AUG 2020 15:32

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**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

27 AUG 2020 07:57

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**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 AUG 2020 14:55

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**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

29 AUG 2020 00:44

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**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 ☐

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 14:54
PC Open Date & Time	22 AUG 2020 14:37
PC Close Date & Time	22 AUG 2020 17:07

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**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 ☐

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

No ☒

Yes ☐

PC Time stamp	23 AUG 2020 00:12
PC Open Date & Time	22 AUG 2020 18:02
PC Close Date & Time	23 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**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 ☒

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 23:35
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

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EAB) (1725)

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 00:48
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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 2780

EAB) (1725)

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 15:34
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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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US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 07:58
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

55 of 2780

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 14:56
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**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 ☒

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 00:44
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3042309

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 14:59:37

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 AUG 2020 12:00
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3042309

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:00:06

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 22:00:06

Generated On: 09 Jun 2021 14:59:37

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)	24 SEP 2020
Time of assessment (00:00-23:59)	08:44 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 08:44
Temperature (xxx.x)	37.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 22:00:06

Generated On: 09 Jun 2021 14:59:37

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:51
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3042309

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3042309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 09:14 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 09:14

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

US3042309

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	08:55 (24 HR)
Collection date and time (derived)	24 SEP 2020 08:55

US3042309

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:50	24 SEP 2020 08:50
Nasopharyngeal Swab 2	No		

US3042309

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

24 SEP 2020 09:54

PC Open Date & Time

24 SEP 2020 09:34

PC Close Date & Time

24 SEP 2020 12:04

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**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 97.2 °F

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

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

PC Time Stamp	24 SEP 2020 13:36
PC Open Date & Time	24 SEP 2020 12:59
PC Close Date & Time	25 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 00:17

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**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

26 SEP 2020 15:44

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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

96.6 °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

27 SEP 2020 19:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 12:00

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 00:07

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**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

24 SEP 2020 09:54

PC Open Date & Time

24 SEP 2020 09:34

PC Close Date & Time

24 SEP 2020 12:04

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**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

24 SEP 2020 13:37

PC Open Date & Time

24 SEP 2020 12:59

PC Close Date & Time

25 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**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

26 SEP 2020 00:17

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**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

26 SEP 2020 15:45

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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

27 SEP 2020 19:04

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**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

28 SEP 2020 12:00

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**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

30 SEP 2020 00:07

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**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 ☐

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 09:55
PC Open Date & Time	24 SEP 2020 09:34
PC Close Date & Time	24 SEP 2020 12:04

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**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 ☐

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 13:38
PC Open Date & Time	24 SEP 2020 12:59
PC Close Date & Time	25 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

94 of 2780

EAB) (1725)

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 00:17
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

96 of 2780

EAB) (1725)

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 15:45
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**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 ☒

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:04
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 12:01
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

102 of 2780

EAB) (1725)

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 00:07
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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 ☐

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Yes ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3042309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3042309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	08:02 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 08:02
Temperature (xxx.x)	36.8 C
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042309

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3042309

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	08:15 (24 HR)
Collection date and time (derived)	22 OCT 2020 08:15

US3042309

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

<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	22 OCT 2020 17:11:14
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3042309

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

29 OCT 2020 13:27:15

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3042309

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 10:05:16
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3042309

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

19 NOV 2020 07:21:26

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 00:22:24
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 15:35:31

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 16:10:55
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 17:47:54

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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	21 DEC 2020 11:15:31
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

28 DEC 2020 00:48:38

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 00:28:21

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 JAN 2021 00:01:36
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

18 JAN 2021 00:31:59

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

25 JAN 2021 06:21:02

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 12:08:08
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

08 FEB 2021 11:25:53

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	17 FEB 2021 08:37:13
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 21:21:04
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 00:04:26
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

08 MAR 2021 11:55:13

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 19:16:39

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

22 MAR 2021 00:02:31

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

29 MAR 2021 00:02:36

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

05 APR 2021 09:40:43

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 19:38:24

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 00:04:23
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 13:08:49

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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

03 MAY 2021 01:59:52

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 264

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

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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21 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUN 2021 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUL 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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="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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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02 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 AUG 2021 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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20 AUG 2021 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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03 SEP 2021 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 SEP 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 SEP 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	04 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 OCT 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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="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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 NOV 2021 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 DEC 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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="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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2021 23:59
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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JAN 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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04 FEB 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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14 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 FEB 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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°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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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14 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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21 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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01 APR 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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08 APR 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 APR 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 APR 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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="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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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02 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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="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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 AUG 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2022 23:59
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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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"/>

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	03 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2022 23:59
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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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°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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

**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 ☐

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

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[Patient Cloud Close Date & Time](#)

---

21 OCT 2022 23:59

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US3042309

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

US3042309

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:59:37

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 00:03:52

US3042309

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3042309

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:05

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042309

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3042309

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

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) \_\_\_\_\_

US3042309

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3042309

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	08:45 (24 HR)
Collection date and time (derived)	09 MAR 2021 08:45

US3042309

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:10

Generated On: 09 Jun 2021 14:59:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3042309**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

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*

**US3042309**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Date of Contact	16 SEP 2020
Time of Contact	13:57
Date and Time of Contact (derived)	16 SEP 2020 13:57
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	37.1 C	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Date of Visit	16 SEP 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	16 SEP 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

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

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

**Data signed: (b) (4) 28 Apr 2021 22:00:04**

**Generated On: 09 Jun 2021 14:59:37**

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3042309

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 SEP 2020
Day 5	Yes	20 SEP 2020
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)	

US3042309

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	SICKD1

US3042309

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:57 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 13:57
Height ( <i>xxx.x</i> )	190.5 cm
Weight ( <i>xxx.x</i> )	139.4 kg
Temperature ( <i>xxx.x</i> )	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	63 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042309

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3042309

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 22:00:04

Generated On: 09 Jun 2021 14:59:37

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 SEP 2020

US3042309

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

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

Visit date (dd MMM yyyy)	13 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3042309

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Date of updated informed consent ( <i>dd MMM yyyy</i> )	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3042309

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00-23:59)	13:33 (24 HR)
Collection date and time (derived)	13 JAN 2021 13:33

US3042309

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	13:35
Collection Date and Time (derived)	13 JAN 2021 13:35

US3042309

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3042309

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID

Adverse event

STREP THROAT

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)

18 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)

29 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

352 of 2780

EAB) (1725)

US3042309

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3042309

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID

Adverse event

MILD SORE THROAT

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)

16 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)

29 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3042309

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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	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)	_____

US3042309

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID

Adverse event

MODERATE CHILLS

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)

16 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)

29 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3042309

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

US3042309

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID

Adverse event

MILD COUGH

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)

16 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)

29 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3042309

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3042309

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID

Adverse event

MODERATE FATIGUE

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)

16 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)

29 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3042309

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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	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)	

US3042309

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID

Adverse event

SEVERE MUSCLE ACHES

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)

16 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)

29 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3042309

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	

US3042309

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID

Adverse event

SEVERE BODY ACHES

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)

16 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)

29 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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:	
<hr/>	
Narrative	
<hr/>	
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)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID

Adverse event

MILD HEADACHE

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)

16 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)

29 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID

Adverse event

MILD NASAL CONGESTION

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)

16 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)

29 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID	
Adverse event	MILD RUNNY NOSE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 22:00:02

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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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID	USA-US052-2021-MRNA-1273-P30 1000005
Adverse event	ABDOMINAL STAB WOUND
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)	13 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 MAR 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 type="radio"/> Grade 4 <input checked="" 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)	13 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	16 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 22:00:02

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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	SUBJECT SUFFERED AN ABDOMINAL STAB WOUND.
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 (12)

Data signed: (b) (4) 28 Apr 2021 22:00:02

Generated On: 09 Jun 2021 14:59:37

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 22:00:02

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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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 22:00:04

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 500

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 22:00:03

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	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 2008	
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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input 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 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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 2008	
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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input 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 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
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 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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 2008	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input 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 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 150

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 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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 2008	
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 (5)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

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 (5)

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	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 2008	
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 22:00:03

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication FATIGUE, GENERALIZED  
MUSCLE AND BODY ACHES,  
HEADACHE DUE TO STREP  
THROAT

Dose per administration 800

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:00:03

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 SEP 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input 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 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication STREP THROAT

Dose per administration 500

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 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 29 SEP 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	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 22:00:03

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Name of Medication SUBOXONE

Prophylaxis Yes ☐  
No ☒

Indication NARCOTIC ABUSE

Dose per administration 16/4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
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 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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 checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	18 FEB 2021	
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 (9)

Data signed: (b) (4) 28 Apr 2021 22:00:03

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Name of Medication AMITHRIPTYLINE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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)	01 JAN 2021	
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 (10)

Data signed: (b) (4) 28 Apr 2021 22:00:03

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Name of Medication CLONIDINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration .4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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 OCT 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 (11)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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 OCT 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 (12)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

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 (12)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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 OCT 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐  
No ☒

Indication LOW TESTOSTERONE

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

Q2WEEKS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication TOPIRAMATS

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL STABBING

Dose per administration 150

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 (14)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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)	16 FEB 2021	
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 (15)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication ZALEPLON

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

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 (15)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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)	16 FEB 2021	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

Name of Medication NICOTINE GUM

Prophylaxis Yes ☐  
No ☒

Indication SMOKING PROPHYLAXIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:00:03

Generated On: 09 Jun 2021 14:59:37

	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 JAN 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3042309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3042309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 FEB 2021	EXPLORATROY LAPAROTOMY	Adverse Event	
13 FEB 2021	ABDOMINAL WALL RECONSTRUCTION	Adverse Event	
13 FEB 2021	TAP BLOCK	Adverse Event	

US3042309

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:59:37

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3042309

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:59:37

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 ☐

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US052-2021-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US052-2021-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/FEB/2021 13:53
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

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US052-2021-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/FEB/2021 08:13
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

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US052-2021-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/MAR/2021 14:58
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

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US052-2021-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/MAR/2021 14:09
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

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US052-2021-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	16/MAR/2021 06:42
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

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US052-2021-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/APR/2021 10:15
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

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US052-2021-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/APR/2021 08:25
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

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 22:00:04

Generated On: 09 Jun 2021 14:59:37

SAEID	USA-US052-2021-MRNA-1273-P301000005
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	27/APR/2021 11:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3042309 (Prod: Meridian Clinical Research)

**US3042309**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:59:37**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'US3042309'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	22 Aug 2020 19:09:12

**US3042309**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:28

**US3042309**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	22 Aug 2020 19:09:14

**US3042309**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:28

**US3042309**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'SCRN'	(b) (4), (b) (6) System	24 Aug 2020 20:18:28

US3042309

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:37

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered (b) (6) 1981'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	22 Aug 2020 19:09:15

US3042309

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:37

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '39'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'YEARS'	(b) (4), (b) (6) System	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered '39'	(b) (4), (b) (6) System	22 Aug 2020 19:50:17

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Male (M)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 20:18:34
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 20:18:34
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

**US3042309**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:59:37**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:34

US3042309

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:37

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '22 Aug 2020'	Rylea Gulick (b) (4)	22 Aug 2020 19:50:17
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'Aug 2020'	(b) (4), (b) (6) System	22 Aug 2020 19:50:17

**US3042309**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered '2020'	(b) (4), (b) (6) System	22 Aug 2020 19:50:17

**US3042309**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Amendment 2 (2)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 19:50:17

**US3042309**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 19:50:17

**US3042309**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Aug 2020 19:50:17
	(b) (4)	

US3042309

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 19:50:17

**US3042309**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	22 Aug 2020 19:50:17
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	RWS_ENDPOINT	22 Aug 2020 19:09:14
	ENDPOINT (b) (4)	
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:59:37**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'I'	(b) (4), (b) (6) System	22 Aug 2020 19:50:20

US3042309

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	22 Aug 2020 19:50:20
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 14:59:37**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:18:55

US3042309

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:21:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:21:37
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 20:20:03
User entered 'MIGRAINES'	Rylea Gulick (b) (4)	24 Aug 2020 20:19:13
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'UN UNK 2008'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:13

**US3042309**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:13

**US3042309**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:13

**US3042309**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:13

**US3042309**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:13

**US3042309**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'Jan 2008'	(b) (4), (b) (6) System	24 Aug 2020 20:19:13

**US3042309**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered '2008'	(b) (4), (b) (6) System	24 Aug 2020 20:19:13

**US3042309**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 20:19:13

**US3042309**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 20:19:13

US3042309

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:21:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 20:21:37
	(b) (4)	
Data point term sent to Coder	System	24 Aug 2020 20:20:03
User entered 'DEPRESSION'	Rylea Gulick (b) (4)	24 Aug 2020 20:19:24
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'UN UNK 2008'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:24

**US3042309**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:24

**US3042309**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:24

**US3042309**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:24

**US3042309**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:24

**US3042309**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'Jan 2008'	(b) (4), (b) (6) System	24 Aug 2020 20:19:24

**US3042309**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered '2008'	(b) (4), (b) (6) System	24 Aug 2020 20:19:24

**US3042309**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 20:19:24

**US3042309**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 20:19:24

US3042309

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Narcotic abuse - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 16:14:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 16:14:43
	(b) (4)	
Data point term sent to Coder	System	02 Mar 2021 16:14:00
User entered 'NARCOTIC ABUSE'	Rylea Gulick (b) (4)	02 Mar 2021 16:13:32
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'UN UNK 2016'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:13:32

**US3042309**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:13:32

**US3042309**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:13:32

**US3042309**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:13:32

**US3042309**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:13:32

**US3042309**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'Jan 2016'	(b) (4), (b) (6) System	02 Mar 2021 16:13:32

**US3042309**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered '2016'	(b) (4), (b) (6) System	02 Mar 2021 16:13:32

**US3042309**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	02 Mar 2021 16:13:32

**US3042309**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	02 Mar 2021 16:13:32

US3042309

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:03:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 14:03:22
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 13:46:13
User entered 'INSOMNIA'	Rylea Gulick (b) (4)	09 Apr 2021 13:45:20
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'UN Jan 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:20

**US3042309**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:20

**US3042309**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:20

**US3042309**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:20

**US3042309**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:20

**US3042309**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'Jan 2020'	(b) (4), (b) (6) System	09 Apr 2021 13:45:20

**US3042309**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered '2020'	(b) (4), (b) (6) System	09 Apr 2021 13:45:20

**US3042309**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	09 Apr 2021 13:45:20

**US3042309**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	09 Apr 2021 13:45:20

US3042309

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:03:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:03:22
Data point term sent to Coder	System	09 Apr 2021 13:46:13
User entered 'LOW TESTOSTERONE'	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:34

**US3042309**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'UN UNK 2016'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:34

**US3042309**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:34

**US3042309**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:34

**US3042309**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:34

**US3042309**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:45:34

**US3042309**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'Jan 2016'	(b) (4), (b) (6) System	09 Apr 2021 13:45:34

**US3042309**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered '2016'	(b) (4), (b) (6) System	09 Apr 2021 13:45:34

**US3042309**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	09 Apr 2021 13:45:34

**US3042309**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered empty.	(b) (4), (b) (6) System	09 Apr 2021 13:45:34

US3042309

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:47

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '22 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:47

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '13:37'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:47

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered '22 Aug 2020 13:37'	(b) (4), (b) (6) System	24 Aug 2020 20:19:47

US3042309

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '190.5' cm	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 20:19:47
DataPoint set to visible.	(b) (4) System	22 Aug 2020 19:50:20

US3042309

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '139.4' kg	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 20:19:47
DataPoint set to visible.	(b) (4) System	22 Aug 2020 19:50:20

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
Amendment Manager: User entered '38.41252'	(b) (4), (b) (6)	
User entered '38.4'	System	17 Sep 2020 00:20:16
DataPoint set to visible.	System	24 Aug 2020 20:19:47
	System	22 Aug 2020 19:50:20

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	24 Aug 2020 20:19:47
DataPoint set to visible.	System	22 Aug 2020 19:50:20

US3042309

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Oct 2020 07:47:54
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:53:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:53:24
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Oct 2020 11:01:09
User entered '37.0' C	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:47

US3042309

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:53:24
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	24 Aug 2020 20:19:47
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:19:47

US3042309

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:53:24
change Data Entry Error	(b) (4)	
User entered '77'	Rylea Gulick (b) (4)	24 Aug 2020 20:19:47
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'bpm'	(b) (4), (b) (6) System	24 Aug 2020 20:19:47

US3042309

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:53:24
change Data Entry Error	(b) (4)	
User entered '16'	Rylea Gulick (b) (4)	24 Aug 2020 20:19:47
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Aug 2020 20:19:47

US3042309

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:53:24
change Data Entry Error	(b) (4)	
User entered '136'	Rylea Gulick (b) (4)	24 Aug 2020 20:19:47
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 20:19:47

US3042309

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:53:24
change Data Entry Error	(b) (4)	
User entered '86'	Rylea Gulick (b) (4)	24 Aug 2020 20:19:47
	(b) (4)	

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 20:19:47

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:24:22

**US3042309**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:24:22

US3042309

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 16:21:09
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 20:19:50
	(b) (4)	

US3042309

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	22 Sep 2020 16:21:09
User entered empty; reason for change Data Entry Error	Jamie Thompson (b) (4)	22 Sep 2020 16:21:09
	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 20:57:26
User entered '22 Aug 2020'	Rylea Gulick (b) (4)	24 Aug 2020 20:19:50
	(b) (4)	

US3042309

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

US3042309

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

US3042309

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

**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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

US3042309

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

**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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

US3042309

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Aug 2020 20:55:15
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 20:24:32
	(b) (4)	

US3042309

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

[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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

US3042309

Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	24 Aug 2020 20:55:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 20:55:15
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:55:15
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 20:24:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

**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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	04 Sep 2020 15:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 20:24:32
	(b) (4)	

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	04 Sep 2020 15:22:41
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 20:24:32
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'WORKS IN HR DEPARTMENT FOR AMAZON; SEES COWORKERS ON A DAILY BASIS' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	04 Sep 2020 15:22:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 20:24:32
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

[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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

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)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:32

**US3042309**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:59:37**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	24 Aug 2020 20:24:32
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:24:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 20:24:32
	(b) (4)	

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:45

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '22 Aug 2020'	Rylea Gulick (b) (4)	24 Aug 2020 20:24:45
	(b) (4)	

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:24:45

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**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'VISIT1'	(b) (4), (b) (6) System	24 Aug 2020 20:24:45

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	22 Aug 2020 19:09:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:37

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '107428'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	22 Aug 2020 19:09:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	22 Aug 2020 19:09:17

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:59:37**

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)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:25:13

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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)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 20:25:13
	(b) (4)	

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:59:37**

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:25:13

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:59:37**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:25:13

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:59:37**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:25:13

US3042309

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:37

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:14:28
	(b) (4), (b) (6)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'ENTRY UPDATED ' (Site from DM).	Rylea Gulick (b) (4)	29 Oct 2020 17:57:54
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	29 Oct 2020 17:57:51
	(b) (4)	
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:21:25
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:22
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:21:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 06:52:26
	(b) (4), (b) (6)	
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.'	Rylea Gulick (b) (4)	29 Oct 2020 13:50:22
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	29 Oct 2020 13:50:18
	(b) (4)	
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:30:10
	(b) (4), (b) (6)	
User entered '190.5' cm	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	29 Oct 2020 13:50:18
change Data Entry Error	(b) (4)	
User entered '139.4' kg	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 06:52:26
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 13:50:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 13:50:18
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 04:30:10
User entered '190.5' cm	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	29 Oct 2020 13:50:18
change Data Entry Error	(b) (4)	
User entered '139.4' kg	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '22 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '13:37'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered '22 Aug 2020 13:37'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '37.0' C	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '77'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'bpm'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '136'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '86'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 06:52:26
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 13:50:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 13:50:18
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 04:30:10
User entered '190.5' cm	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	29 Oct 2020 13:50:18
change Data Entry Error	(b) (4)	
User entered '139.4' kg	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '22 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '14:57'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered '22 Aug 2020 14:57'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

US3042309

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '36.8' C	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '66'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'bpm'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:26
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '134'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '84'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:26

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 20:26:26

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '22 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:31

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	22 Aug 2020 19:50:31
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Aug 2020 19:50:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Aug 2020 19:50:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '22 Aug 2020'	Rylea Gulick (b) (4)	22 Aug 2020 19:50:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '14:17'	Rylea Gulick (b) (4)	22 Aug 2020 19:50:31
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered '22 Aug 2020 14:17'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4)	22 Aug 2020 19:50:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'ONCE'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	24 Aug 2020 20:26:42
	(b) (4)	

US3042309

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '22 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:42

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '14:03'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:42
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered '22 Aug 2020 14:03'	(b) (4), (b) (6) System	24 Aug 2020 20:26:42

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:59:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '22 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:57

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	24 Aug 2020 20:26:57
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:57

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 16:44:37
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	04 Sep 2020 16:44:37
User entered '13:50' reason for change: Data Entry Error	Rylea Gulick (b) (4)	04 Sep 2020 16:44:37
	(b) (4)	
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	24 Aug 2020 20:26:57
User entered empty.	Rylea Gulick (b) (4)	24 Aug 2020 20:26:57
	(b) (4)	

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered '22 Aug 2020 13:50'	(b) (4), (b) (6)	
	System	04 Sep 2020 16:44:37
User entered empty.	System	24 Aug 2020 20:26:57

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:57

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:57

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:26:57

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 20:26:57

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Aug 2020 20:27:01
	(b) (4)	

**US3042309**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:03:25
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 20:27:01

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:52:28', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '14b43b88-d1b0-4d97-8989-f801266159f6' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 19:53:08
	System	22 Aug 2020 19:53:08

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:52:54', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '14b43b88-d1b0-4d97-8989-f801266159f6' User entered '98.2'	(b) (4), (b) (6) System	22 Aug 2020 19:53:08
	System	22 Aug 2020 19:53:08

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:53:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '14b43b88-d1b0-4d97-8989-f801266159f6' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 19:53:08
	System	22 Aug 2020 19:53:08

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:53:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '14b43b88-d1b0-4d97-8989-f801266159f6' User entered '22 Aug 2020 14:53'	(b) (4), (b) (6) System	22 Aug 2020 19:53:08
	System	22 Aug 2020 19:53:08

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '22 Aug 2020 14:37'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '22 Aug 2020 17:07'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:09:42', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bde38927-3e6d-4b88-bfed-3660d6bbf637'	(b) (4), (b) (6)	
	System	23 Aug 2020 05:10:51
User entered 'Yes (Y)'	System	23 Aug 2020 05:10:51

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:09:52', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bde38927-3e6d-4b88-bfed-3660d6bbf637' User entered '97.8'	(b) (4), (b) (6) System	23 Aug 2020 05:10:51
	System	23 Aug 2020 05:10:51

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:09:59', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bde38927-3e6d-4b88-bfed-3660d6bbf637'	(b) (4), (b) (6)	
	System	23 Aug 2020 05:10:51
User entered 'Yes (Y)'	System	23 Aug 2020 05:10:51

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
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 'SUBJECT STATED SYMPTOMS THEY REPORTED WERE USUAL; RELATED TO MIGRAINES AND MUSCLE ACHES ARE PER USUAL.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Sep 2020 06:32:32
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.'	Rylea Gulick (b) (4) (b) (4)	04 Sep 2020 16:46:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:10:24', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bde38927-3e6d-4b88-bfed-3660d6bbf637'	System	23 Aug 2020 05:10:51
User entered '1'	System	23 Aug 2020 05:10:51

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:10:24', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bde38927-3e6d-4b88-bfed-3660d6bbf637' User entered '0'	(b) (4), (b) (6) System	23 Aug 2020 05:10:51
	System	23 Aug 2020 05:10:51

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:10:49', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bde38927-3e6d-4b88-bfed-3660d6bbf637' User entered '23 Aug 2020 00:10'	(b) (4), (b) (6) System	23 Aug 2020 05:10:51
	System	23 Aug 2020 05:10:51

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '22 Aug 2020 18:02'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 2'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:30:57', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ea3a7e70-276f-4e8f-8c73-bfbe744bb050' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Aug 2020 04:33:08
	System	24 Aug 2020 04:33:08

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:32:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ea3a7e70-276f-4e8f-8c73-bfbe744bb050' User entered '96.0'	(b) (4), (b) (6) System	24 Aug 2020 04:33:08
	System	24 Aug 2020 04:33:08

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:32:41', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ea3a7e70-276f-4e8f-8c73-bfbe744bb050'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	24 Aug 2020 04:33:08

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
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 'SUBJECT STATED SYMPTOMS THEY REPORTED WERE USUAL; RELATED TO MIGRAINES AND MUSCLE ACHES ARE PER USUAL.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Sep 2020 06:32:45
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.'	Rylea Gulick (b) (4) (b) (4)	04 Sep 2020 16:46:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:32:59', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ea3a7e70-276f-4e8f-8c73-bf744bb050'	System	24 Aug 2020 04:33:08
User entered '1'	System	24 Aug 2020 04:33:08

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:32:59', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ea3a7e70-276f-4e8f-8c73-bfbe744bb050' User entered '0'	(b) (4), (b) (6) System	24 Aug 2020 04:33:08
	System	24 Aug 2020 04:33:08

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:33:03', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ea3a7e70-276f-4e8f-8c73-bfbe744bb050' User entered '23 Aug 2020 23:33'	(b) (4), (b) (6) System	24 Aug 2020 04:33:08
	System	24 Aug 2020 04:33:08

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 3'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:47:34', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5e06ff6f-27d9-4a9e-9fff-2af71088ed43'	(b) (4), (b) (6)	
	System	25 Aug 2020 05:47:49
User entered 'Yes (Y)'	System	25 Aug 2020 05:47:49

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:47:40', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5e06ff6f-27d9-4a9e-9fff-2af71088ed43' User entered '97.0'	(b) (4), (b) (6) System	25 Aug 2020 05:47:49
	System	25 Aug 2020 05:47:49

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:47:43', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5e06ff6f-27d9-4a9e-9fff-2af71088ed43'	(b) (4), (b) (6)	
	System	25 Aug 2020 05:47:49
User entered 'No (N)'	System	25 Aug 2020 05:47:49

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:47:47', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5e06ff6f-27d9-4a9e-9fff-2af71088ed43'	(b) (4), (b) (6)	
	System	25 Aug 2020 05:47:49
User entered '25 Aug 2020 00:47'	System	25 Aug 2020 05:47:49

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 4'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:31:26', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '78619f77-3c06-49c2-81a8-175e1b4d0724' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Aug 2020 20:31:59
	System	25 Aug 2020 20:31:59

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:31:50', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '78619f77-3c06-49c2-81a8-175e1b4d0724' User entered '97.2'	(b) (4), (b) (6) System	25 Aug 2020 20:31:59
	System	25 Aug 2020 20:31:59

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:31:54', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '78619f77-3c06-49c2-81a8-175e1b4d0724'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Aug 2020 20:31:59

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:31:58', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '78619f77-3c06-49c2-81a8-175e1b4d0724' User entered '25 Aug 2020 15:31'	(b) (4), (b) (6) System	25 Aug 2020 20:31:59
	System	25 Aug 2020 20:31:59

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 5'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:56:54', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '4ad5a640-da17-402f-9835-6f569220364b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 12:57:37
	System	27 Aug 2020 12:57:37

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:02', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '4ad5a640-da17-402f-9835-6f569220364b' User entered '97.5'	(b) (4), (b) (6) System	27 Aug 2020 12:57:37
	System	27 Aug 2020 12:57:37

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:06', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '4ad5a640-da17-402f-9835-6f569220364b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 12:57:37
	System	27 Aug 2020 12:57:37

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
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 'SUBJECT STATED SYMPTOMS THEY REPORTED WERE USUAL; RELATED TO MIGRAINES AND MUSCLE ACHES ARE PER USUAL.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Sep 2020 06:33:33
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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:27', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '4ad5a640-da17-402f-9835-6f569220364b' User entered '1'	Rylea Gulick (b) (4) (b) (4)	04 Sep 2020 16:46:34
	System	27 Aug 2020 12:57:37
	System	27 Aug 2020 12:57:37
	System	27 Aug 2020 12:57:37

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:27', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '4ad5a640-da17-402f-9835-6f569220364b' User entered '0'	(b) (4), (b) (6) System	27 Aug 2020 12:57:37
	System	27 Aug 2020 12:57:37

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '4ad5a640-da17-402f-9835-6f569220364b' User entered '27 Aug 2020 07:57'	(b) (4), (b) (6) System	27 Aug 2020 12:57:37
	System	27 Aug 2020 12:57:37

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 6'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:11', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0a4ab975-3132-4b76-b643-dc8c0b6ce7ed' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 19:55:37
	System	27 Aug 2020 19:55:37

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:18', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0a4ab975-3132-4b76-b643-dc8c0b6ce7ed' User entered '97.0'	(b) (4), (b) (6) System	27 Aug 2020 19:55:37
	System	27 Aug 2020 19:55:37

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:21', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0a4ab975-3132-4b76-b643-dc8c0b6ce7ed' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 19:55:37
	System	27 Aug 2020 19:55:37

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
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 'SUBJECT STATED SYMPTOMS THEY REPORTED WERE USUAL; RELATED TO MIGRAINES AND MUSCLE ACHES ARE PER USUAL.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Sep 2020 06:34:51
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.'	Rylea Gulick (b) (4) (b) (4)	04 Sep 2020 16:46:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:25', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0a4ab975-3132-4b76-b643-dc8c0b6ce7ed'	System	27 Aug 2020 19:55:37
User entered '1'	System	27 Aug 2020 19:55:37

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:25', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0a4ab975-3132-4b76-b643-dc8c0b6ce7ed' User entered '0'	(b) (4), (b) (6) System	27 Aug 2020 19:55:37
	System	27 Aug 2020 19:55:37

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0a4ab975-3132-4b76-b643-dc8c0b6ce7ed' User entered '27 Aug 2020 14:55'	(b) (4), (b) (6) System	27 Aug 2020 19:55:37
	System	27 Aug 2020 19:55:37

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 7'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:43:43', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '20b6ea46-e380-45aa-ac65-8bf206bd264d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:01
	System	29 Aug 2020 05:44:01

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:43:49', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '20b6ea46-e380-45aa-ac65-8bf206bd264d' User entered '97.7'	(b) (4), (b) (6) System	29 Aug 2020 05:44:01
	System	29 Aug 2020 05:44:01

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:43:53', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '20b6ea46-e380-45aa-ac65-8bf206bd264d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:01
	System	29 Aug 2020 05:44:01

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
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 'SUBJECT STATED SYMPTOMS THEY REPORTED WERE USUAL; RELATED TO MIGRAINES AND MUSCLE ACHES ARE PER USUAL.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Sep 2020 06:22:15
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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:43:55', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '20b6ea46-e380-45aa-ac65-8bf206bd264d' User entered '1'	Rylea Gulick (b) (4) (b) (4)	04 Sep 2020 16:46:43
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	29 Aug 2020 05:44:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:43:55', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '20b6ea46-e380-45aa-ac65-8bf206bd264d' User entered '1'	System	29 Aug 2020 05:44:01
User entered '1'	System	29 Aug 2020 05:44:01

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:43:55', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '20b6ea46-e380-45aa-ac65-8bf206bd264d' User entered '0'	(b) (4), (b) (6) System	29 Aug 2020 05:44:01
	System	29 Aug 2020 05:44:01

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:43:59', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '20b6ea46-e380-45aa-ac65-8bf206bd264d' User entered '29 Aug 2020 00:43'	(b) (4), (b) (6) System	29 Aug 2020 05:44:01
	System	29 Aug 2020 05:44:01

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:55:37
User entered 'Day 8'	System	27 Aug 2020 19:55:37

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T12:00:14', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2a6cd7cd-74ce-4d5f-8b78-e17f1cabbcbce' User entered 'Yes (Y)'	(b) (4), (b) (6) System	29 Aug 2020 17:00:32
	System	29 Aug 2020 17:00:32

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T12:00:20', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2a6cd7cd-74ce-4d5f-8b78-e17f1cabbcbce' User entered '97.1'	(b) (4), (b) (6) System	29 Aug 2020 17:00:32
	System	29 Aug 2020 17:00:32

US3042309

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T12:00:23', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2a6cd7cd-74ce-4d5f-8b78-e17f1cabbcb'	(b) (4), (b) (6)	
	System	29 Aug 2020 17:00:32
User entered 'No (N)'	System	29 Aug 2020 17:00:32

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T12:00:26', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2a6cd7cd-74ce-4d5f-8b78-e17f1cabbcbce' User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Aug 2020 17:00:32
	System	29 Aug 2020 17:00:32

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:55:37

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '30 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:55:37

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:53:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '53f6d0cc-cef1-4a68-b50d-29b5e70e6418' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 19:53:52
	System	22 Aug 2020 19:53:52

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:53:37', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '53f6d0cc-cef1-4a68-b50d-29b5e70e6418' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 19:53:52
	System	22 Aug 2020 19:53:52

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:53:40', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '53f6d0cc-cef1-4a68-b50d-29b5e70e6418' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 19:53:52
	System	22 Aug 2020 19:53:52

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:53:47', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '53f6d0cc-cef1-4a68-b50d-29b5e70e6418' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 19:53:52
	System	22 Aug 2020 19:53:52

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:53:50', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '53f6d0cc-cef1-4a68-b50d-29b5e70e6418' User entered '22 Aug 2020 14:53'	(b) (4), (b) (6) System	22 Aug 2020 19:53:52
	System	22 Aug 2020 19:53:52

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '22 Aug 2020 14:37'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '22 Aug 2020 17:07'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:11:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a9314d29-a4e7-42c6-acbe-d337a60d4efc' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 05:11:39
	System	23 Aug 2020 05:11:39

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:11:18', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a9314d29-a4e7-42c6-acbe-d337a60d4efc' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 05:11:39
	System	23 Aug 2020 05:11:39

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:11:21', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a9314d29-a4e7-42c6-acbe-d337a60d4efc' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 05:11:39
	System	23 Aug 2020 05:11:39

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:11:31', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a9314d29-a4e7-42c6-acbe-d337a60d4efc' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 05:11:39
	System	23 Aug 2020 05:11:39

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:11:37', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a9314d29-a4e7-42c6-acbe-d337a60d4efc' User entered '23 Aug 2020 00:11'	(b) (4), (b) (6) System	23 Aug 2020 05:11:39
	System	23 Aug 2020 05:11:39

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '22 Aug 2020 18:02'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 2'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:33:38', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd093fbfb-535f-4201-93c1-d5134eeb0d9a' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 04:33:56
	System	24 Aug 2020 04:33:56

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:33:41', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd093fbfb-535f-4201-93c1-d5134eeb0d9a' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 04:33:56
	System	24 Aug 2020 04:33:56

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:33:44', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd093fbfb-535f-4201-93c1-d5134eeb0d9a' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 04:33:56
	System	24 Aug 2020 04:33:56

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:33:48', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd093fbfb-535f-4201-93c1-d5134eeb0d9a' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 04:33:56
	System	24 Aug 2020 04:33:56

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:33:53', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd093fbfb-535f-4201-93c1-d5134eeb0d9a' User entered '23 Aug 2020 23:33'	(b) (4), (b) (6) System	24 Aug 2020 04:33:56
	System	24 Aug 2020 04:33:56

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 3'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:47:51', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'b142ff0c-afaa-433b-9367-dc9c78610e3a'	(b) (4), (b) (6)	
	System	25 Aug 2020 05:48:10
User entered 'None (1)'	System	25 Aug 2020 05:48:10

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:47:54', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'b142ff0c-afaa-433b-9367-dc9c78610e3a' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 05:48:10
	System	25 Aug 2020 05:48:10

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:47:57', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'b142ff0c-afaa-433b-9367-dc9c78610e3a'	(b) (4), (b) (6) System	25 Aug 2020 05:48:10
User entered 'No (N)'	System	25 Aug 2020 05:48:10

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:01', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'b142ff0c-afaa-433b-9367-dc9c78610e3a' User entered 'None (1)'	(b) (4), (b) (6) System	25 Aug 2020 05:48:10
	System	25 Aug 2020 05:48:10

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'b142ff0c-afaa-433b-9367-dc9c78610e3a' User entered '25 Aug 2020 00:48'	(b) (4), (b) (6) System	25 Aug 2020 05:48:10
	System	25 Aug 2020 05:48:10

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 4'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:32:25', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bbae7cad-8c78-4b98-a653-5dbdfcf4b38b' User entered 'None (1)'	(b) (4), (b) (6) System	25 Aug 2020 20:32:53
	System	25 Aug 2020 20:32:53

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:32:29', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bbae7cad-8c78-4b98-a653-5dbdfcf4b38b' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 20:32:53
	System	25 Aug 2020 20:32:53

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:32:32', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bbae7cad-8c78-4b98-a653-5dbdfcf4b38b' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 20:32:53
	System	25 Aug 2020 20:32:53

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:32:35', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bbae7cad-8c78-4b98-a653-5dbdfcf4b38b' User entered 'None (1)'	(b) (4), (b) (6) System	25 Aug 2020 20:32:53
	System	25 Aug 2020 20:32:53

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:32:52', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bbae7cad-8c78-4b98-a653-5dbdfcf4b38b' User entered '25 Aug 2020 15:32'	(b) (4), (b) (6) System	25 Aug 2020 20:32:53
	System	25 Aug 2020 20:32:53

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 5'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:38', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '164142cb-521e-46ab-b986-71e6016084b3'	(b) (4), (b) (6)	
	System	27 Aug 2020 12:57:49
User entered 'None (1)'	System	27 Aug 2020 12:57:49

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:41', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '164142cb-521e-46ab-b986-71e6016084b3' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 12:57:49
	System	27 Aug 2020 12:57:49

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:43', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '164142cb-521e-46ab-b986-71e6016084b3' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 12:57:49
	System	27 Aug 2020 12:57:49

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:45', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '164142cb-521e-46ab-b986-71e6016084b3'	(b) (4), (b) (6)	27 Aug 2020 12:57:49
User entered 'None (1)'	System	27 Aug 2020 12:57:49

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:57:47', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '164142cb-521e-46ab-b986-71e6016084b3' User entered '27 Aug 2020 07:57'	(b) (4), (b) (6) System	27 Aug 2020 12:57:49
	System	27 Aug 2020 12:57:49

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 6'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:36', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'edb80830-845c-4aa2-a97b-c11eeae5b3aa' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 19:55:48
	System	27 Aug 2020 19:55:48

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:39', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'edb80830-845c-4aa2-a97b-c11eeae5b3aa' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 19:55:48
	System	27 Aug 2020 19:55:48

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:41', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'edb80830-845c-4aa2-a97b-c11eeae5b3aa' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 19:55:48
	System	27 Aug 2020 19:55:48

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:43', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'edb80830-845c-4aa2-a97b-c11eeae5b3aa' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 19:55:48
	System	27 Aug 2020 19:55:48

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:46', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'edb80830-845c-4aa2-a97b-c11eeae5b3aa' User entered '27 Aug 2020 14:55'	(b) (4), (b) (6) System	27 Aug 2020 19:55:48
	System	27 Aug 2020 19:55:48

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 7'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:02', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '341918ce-dd87-419d-ac8f-7c7de223f1d8' User entered 'None (1)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:15
	System	29 Aug 2020 05:44:15

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '341918ce-dd87-419d-ac8f-7c7de223f1d8' User entered 'No (N)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:15
	System	29 Aug 2020 05:44:15

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:07', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '341918ce-dd87-419d-ac8f-7c7de223f1d8' User entered 'No (N)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:15
	System	29 Aug 2020 05:44:15

US3042309

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:09', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '341918ce-dd87-419d-ac8f-7c7de223f1d8' User entered 'None (1)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:15
	System	29 Aug 2020 05:44:15

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:11', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '341918ce-dd87-419d-ac8f-7c7de223f1d8' User entered '29 Aug 2020 00:44'	(b) (4), (b) (6) System	29 Aug 2020 05:44:15
	System	29 Aug 2020 05:44:15

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:53:57', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8f6f6c57-145f-441b-896f-a269342dd438' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 19:54:25
	System	22 Aug 2020 19:54:25

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:54:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8f6f6c57-145f-441b-896f-a269342dd438' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 19:54:25
	System	22 Aug 2020 19:54:25

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:54:02', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8f6f6c57-145f-441b-896f-a269342dd438' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 19:54:25
	System	22 Aug 2020 19:54:25

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:54:06', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8f6f6c57-145f-441b-896f-a269342dd438' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 19:54:25
	System	22 Aug 2020 19:54:25

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:54:08', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8f6f6c57-145f-441b-896f-a269342dd438' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 19:54:25
	System	22 Aug 2020 19:54:25

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:54:10', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8f6f6c57-145f-441b-896f-a269342dd438' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 19:54:25
	System	22 Aug 2020 19:54:25

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:54:18', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8f6f6c57-145f-441b-896f-a269342dd438' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 19:54:25
	System	22 Aug 2020 19:54:25

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-22T14:54:23', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8f6f6c57-145f-441b-896f-a269342dd438'	(b) (4), (b) (6) System	22 Aug 2020 19:54:25
User entered '22 Aug 2020 14:54'	System	22 Aug 2020 19:54:25

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '22 Aug 2020 14:37'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '22 Aug 2020 17:07'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:11:45', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e907b9b8-6530-4d1b-9435-a3253bc55fbf' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:12:17
	System	23 Aug 2020 05:12:17

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:11:50', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e907b9b8-6530-4d1b-9435-a3253bc55fbf' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:12:17
	System	23 Aug 2020 05:12:17

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:11:53', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e907b9b8-6530-4d1b-9435-a3253bc55fbf' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:12:17
	System	23 Aug 2020 05:12:17

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:11:56', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e907b9b8-6530-4d1b-9435-a3253bc55fbf' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:12:17
	System	23 Aug 2020 05:12:17

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:12:03', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e907b9b8-6530-4d1b-9435-a3253bc55fbf' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:12:17
	System	23 Aug 2020 05:12:17

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:12:07', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e907b9b8-6530-4d1b-9435-a3253bc55fbf' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 05:12:17
	System	23 Aug 2020 05:12:17

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:12:12', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e907b9b8-6530-4d1b-9435-a3253bc55fbf' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 05:12:17
	System	23 Aug 2020 05:12:17

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T00:12:15', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e907b9b8-6530-4d1b-9435-a3253bc55fbf' User entered '23 Aug 2020 00:12'	(b) (4), (b) (6) System	23 Aug 2020 05:12:17
	System	23 Aug 2020 05:12:17

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '22 Aug 2020 18:02'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 2'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with 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). Query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with 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.' answered with 'SUBJECT TOOK MEDICATION FOR USUAL MIGRAINES' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Sep 2020 05:37:49
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with 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.'	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 16:23:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:34:20', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '17087dd9-eb40-4ab3-863a-d30f6fa7f164'	(b) (4), (b) (6)	09 Sep 2020 11:07:35
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Aug 2020 04:35:05

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:34:25', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '17087dd9-eb40-4ab3-863a-d30f6fa7f164'	(b) (4), (b) (6) System	24 Aug 2020 04:35:05
User entered 'Some interference with activity (2)'	System	24 Aug 2020 04:35:05

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:34:34', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '17087dd9-eb40-4ab3-863a-d30f6fa7f164' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 04:35:05
	System	24 Aug 2020 04:35:05

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:34:44', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '17087dd9-eb40-4ab3-863a-d30f6fa7f164' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 04:35:05
	System	24 Aug 2020 04:35:05

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:34:47', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '17087dd9-eb40-4ab3-863a-d30f6fa7f164' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 04:35:05
	System	24 Aug 2020 04:35:05

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:34:50', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '17087dd9-eb40-4ab3-863a-d30f6fa7f164' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 04:35:05
	System	24 Aug 2020 04:35:05

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:34:55', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '17087dd9-eb40-4ab3-863a-d30f6fa7f164' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 04:35:05
	System	24 Aug 2020 04:35:05

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-23T23:35:02', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '17087dd9-eb40-4ab3-863a-d30f6fa7f164' User entered '23 Aug 2020 23:35'	(b) (4), (b) (6) System	24 Aug 2020 04:35:05
	System	24 Aug 2020 04:35:05

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 3'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:09', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3ca9e4cf-bc6f-4e38-94ac-236a5e1de4df' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:48:37
	System	25 Aug 2020 05:48:37

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:13', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3ca9e4cf-bc6f-4e38-94ac-236a5e1de4df' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:48:37
	System	25 Aug 2020 05:48:37

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:15', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3ca9e4cf-bc6f-4e38-94ac-236a5e1de4df' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:48:37
	System	25 Aug 2020 05:48:37

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:18', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3ca9e4cf-bc6f-4e38-94ac-236a5e1de4df' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:48:37
	System	25 Aug 2020 05:48:37

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:21', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3ca9e4cf-bc6f-4e38-94ac-236a5e1de4df' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:48:37
	System	25 Aug 2020 05:48:37

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:23', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3ca9e4cf-bc6f-4e38-94ac-236a5e1de4df' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 05:48:37
	System	25 Aug 2020 05:48:37

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:29', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3ca9e4cf-bc6f-4e38-94ac-236a5e1de4df' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 05:48:37
	System	25 Aug 2020 05:48:37

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T00:48:31', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3ca9e4cf-bc6f-4e38-94ac-236a5e1de4df' User entered '25 Aug 2020 00:48'	(b) (4), (b) (6) System	25 Aug 2020 05:48:37
	System	25 Aug 2020 05:48:37

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 4'	System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:32:58', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2d3ac4e9-c561-4d68-acc5-cc0c49dab846' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 20:34:15
	System	25 Aug 2020 20:34:15

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:33:38', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2d3ac4e9-c561-4d68-acc5-cc0c49dab846' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 20:34:15
	System	25 Aug 2020 20:34:15

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:33:52', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2d3ac4e9-c561-4d68-acc5-cc0c49dab846' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 20:34:15
	System	25 Aug 2020 20:34:15

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:33:59', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2d3ac4e9-c561-4d68-acc5-cc0c49dab846' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 20:34:15
	System	25 Aug 2020 20:34:15

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:34:01', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2d3ac4e9-c561-4d68-acc5-cc0c49dab846' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 20:34:15
	System	25 Aug 2020 20:34:15

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:34:03', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2d3ac4e9-c561-4d68-acc5-cc0c49dab846' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 20:34:15
	System	25 Aug 2020 20:34:15

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:34:10', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2d3ac4e9-c561-4d68-acc5-cc0c49dab846' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 20:34:15
	System	25 Aug 2020 20:34:15

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-25T15:34:13', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '2d3ac4e9-c561-4d68-acc5-cc0c49dab846' User entered '25 Aug 2020 15:34'	(b) (4), (b) (6) System	25 Aug 2020 20:34:15
	System	25 Aug 2020 20:34:15

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 5'	System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:58:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0647da91-7258-4361-a399-f90c2ec329a5' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	27 Aug 2020 12:58:52
	System	27 Aug 2020 12:58:52

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:58:03', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0647da91-7258-4361-a399-f90c2ec329a5'	(b) (4), (b) (6)	
	System	27 Aug 2020 12:58:52
User entered 'No interference with activity (1)'	System	27 Aug 2020 12:58:52

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:58:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0647da91-7258-4361-a399-f90c2ec329a5' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	27 Aug 2020 12:58:52
	System	27 Aug 2020 12:58:52

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:58:07', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0647da91-7258-4361-a399-f90c2ec329a5' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	27 Aug 2020 12:58:52
	System	27 Aug 2020 12:58:52

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:58:16', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0647da91-7258-4361-a399-f90c2ec329a5' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 12:58:52
	System	27 Aug 2020 12:58:52

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:58:19', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0647da91-7258-4361-a399-f90c2ec329a5' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 12:58:52
	System	27 Aug 2020 12:58:52

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:58:45', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0647da91-7258-4361-a399-f90c2ec329a5' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 12:58:52
	System	27 Aug 2020 12:58:52

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T07:58:48', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0647da91-7258-4361-a399-f90c2ec329a5' User entered '27 Aug 2020 07:58'	(b) (4), (b) (6) System	27 Aug 2020 12:58:52
	System	27 Aug 2020 12:58:52

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 6'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:55:56', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '708a4f13-4196-4538-bf8f-803194b52e89'	(b) (4), (b) (6)	
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	27 Aug 2020 19:56:28

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:56:04', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '708a4f13-4196-4538-bf8f-803194b52e89'	(b) (4), (b) (6)	
	System	27 Aug 2020 19:56:28
User entered 'Some interference with activity (2)'	System	27 Aug 2020 19:56:28

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:56:09', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '708a4f13-4196-4538-bf8f-803194b52e89' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 19:56:28
	System	27 Aug 2020 19:56:28

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:56:14', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '708a4f13-4196-4538-bf8f-803194b52e89' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 19:56:28
	System	27 Aug 2020 19:56:28

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:56:16', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '708a4f13-4196-4538-bf8f-803194b52e89' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 19:56:28
	System	27 Aug 2020 19:56:28

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:56:18', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '708a4f13-4196-4538-bf8f-803194b52e89' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 19:56:28
	System	27 Aug 2020 19:56:28

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:56:22', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '708a4f13-4196-4538-bf8f-803194b52e89' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 19:56:28
	System	27 Aug 2020 19:56:28

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-27T14:56:24', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '708a4f13-4196-4538-bf8f-803194b52e89' User entered '27 Aug 2020 14:56'	(b) (4), (b) (6) System	27 Aug 2020 19:56:28
	System	27 Aug 2020 19:56:28

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 7'	System	22 Aug 2020 19:50:31

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:16', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c0a13e11-adb7-4755-acde-dc47766d80cb' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:36
	System	29 Aug 2020 05:44:36

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:18', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c0a13e11-adb7-4755-acde-dc47766d80cb' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:36
	System	29 Aug 2020 05:44:36

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:21', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c0a13e11-adb7-4755-acde-dc47766d80cb' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:36
	System	29 Aug 2020 05:44:36

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:23', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c0a13e11-adb7-4755-acde-dc47766d80cb' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:36
	System	29 Aug 2020 05:44:36

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:25', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c0a13e11-adb7-4755-acde-dc47766d80cb' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:36
	System	29 Aug 2020 05:44:36

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:27', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c0a13e11-adb7-4755-acde-dc47766d80cb' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:36
	System	29 Aug 2020 05:44:36

US3042309

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:30', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c0a13e11-adb7-4755-acde-dc47766d80cb' User entered 'No (N)'	(b) (4), (b) (6) System	29 Aug 2020 05:44:36
	System	29 Aug 2020 05:44:36

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T00:44:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c0a13e11-adb7-4755-acde-dc47766d80cb' User entered '29 Aug 2020 00:44'	(b) (4), (b) (6) System	29 Aug 2020 05:44:36
	System	29 Aug 2020 05:44:36

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	22 Aug 2020 19:50:31

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:55:37
User entered 'Day 8'	System	27 Aug 2020 19:55:37

US3042309

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T12:00:31', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'addc5c25-f2aa-475c-a8f8-30bfa2a94e6a' User entered 'No (N)'	(b) (4), (b) (6) System	29 Aug 2020 17:00:39
	System	29 Aug 2020 17:00:39

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-08-29T12:00:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'addc5c25-f2aa-475c-a8f8-30bfa2a94e6a' User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	29 Aug 2020 17:00:39
	System	29 Aug 2020 17:00:39

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:55:37

**US3042309**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '30 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:55:37

**US3042309**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:32
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Sep 2020 14:18:54
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:32
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '31 Aug 2020'	Rylea Gulick (b) (4)	15 Sep 2020 14:18:54
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:32
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	15 Sep 2020 14:18:54

**US3042309**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 14:18:54

**US3042309**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:32
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Sep 2020 14:18:57
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:32
User entered 'I'	(b) (4), (b) (6) System	15 Sep 2020 14:18:57

**US3042309**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:05
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Sep 2020 14:19:22
	(b) (4)	

US3042309

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:05
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	16 Sep 2020 03:35:56
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'THIS IS WHEN PT WAS CONTACTED' (Site from System).	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 14:19:57
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 14:19:22
User entered '09 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 14:19:22

**US3042309**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:05
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Sep 2020 14:19:22

**US3042309**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:05
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Sep 2020 14:19:22
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:05
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Sep 2020 14:20:01
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:05
User entered '1'	(b) (4), (b) (6) System	15 Sep 2020 14:20:01

**US3042309**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:45:18
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Sep 2020 14:20:13
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:45:18
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '15 Sep 2020'	Rylea Gulick (b) (4)	15 Sep 2020 14:20:13
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:45:18
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	15 Sep 2020 14:20:13
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:45:18
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Sep 2020 14:20:13
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:45:18
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Sep 2020 14:20:16
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:45:18
User entered 'I'	(b) (4), (b) (6) System	15 Sep 2020 14:20:16

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Sep 2020 15:09:46
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '24 Sep 2020'	Rylea Gulick (b) (4)	24 Sep 2020 15:09:46
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	24 Sep 2020 15:09:46
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'VISIT2'	(b) (4), (b) (6) System	24 Sep 2020 15:09:46

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '24 Sep 2020'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '08:44'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered '24 Sep 2020 08:44'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '37.9' C	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '63'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'bpm'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '138'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '90'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:11:26

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '24 Sep 2020'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '09:51'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered '24 Sep 2020 09:51'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '37.0' C	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '67'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'bpm'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '12'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '134'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

US3042309

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '84'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:26
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 15:11:26

US3042309

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:30
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '24 Sep 2020'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:30
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Sep 2020 14:53:11
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 14:53:11
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 14:53:11
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '24 Sep 2020'	Rylea Gulick (b) (4)	24 Sep 2020 14:53:11
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '09:14'	Rylea Gulick (b) (4)	24 Sep 2020 14:53:11
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered '24 Sep 2020 09:14'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4)	24 Sep 2020 14:53:11
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'ONCE'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 15:11:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 15:11:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Sep 2020 15:11:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 14:59:27
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 14:59:27
	(b) (4)	

US3042309

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '24 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Sep 2020 15:11:45
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 14:59:27
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '08:55' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Sep 2020 15:11:45
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 14:59:27
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User entered '24 Sep 2020 08:55'	System	24 Sep 2020 15:11:45
User entered empty.	System	24 Sep 2020 14:59:27

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 14:59:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '24 Sep 2020'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:52
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:52
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:52
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '08:50'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:52
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered '24 Sep 2020 08:50'	(b) (4), (b) (6) System	24 Sep 2020 15:11:52

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:11:52

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:52
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 15:11:52
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 15:11:52

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	24 Sep 2020 15:11:54
	(b) (4)	

**US3042309**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:12:11
User entered '1'	(b) (4), (b) (6) System	24 Sep 2020 15:11:54

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:53:32', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c7708e73-5ffa-48bd-9fbf-29898f13e19c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Sep 2020 14:54:04
	System	24 Sep 2020 14:54:04

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:53:42', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c7708e73-5ffa-48bd-9fbf-29898f13e19c' User entered '98.6'	(b) (4), (b) (6) System	24 Sep 2020 14:54:04
	System	24 Sep 2020 14:54:04

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:53:46', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c7708e73-5ffa-48bd-9fbf-29898f13e19c' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 14:54:04
	System	24 Sep 2020 14:54:04

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:54:01', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c7708e73-5ffa-48bd-9fbf-29898f13e19c' User entered '24 Sep 2020 09:54'	(b) (4), (b) (6) System	24 Sep 2020 14:54:04
	System	24 Sep 2020 14:54:04

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Sep 2020 09:34'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Sep 2020 12:04'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:36:40', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a9d32b28-afed-4c33-8154-4d75488d59ad' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Sep 2020 18:36:56
	System	24 Sep 2020 18:36:56

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:36:45', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a9d32b28-afed-4c33-8154-4d75488d59ad' User entered '97.2'	(b) (4), (b) (6) System	24 Sep 2020 18:36:56
	System	24 Sep 2020 18:36:56

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:36:48', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a9d32b28-afed-4c33-8154-4d75488d59ad' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 18:36:56
	System	24 Sep 2020 18:36:56

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:36:52', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a9d32b28-afed-4c33-8154-4d75488d59ad' User entered '24 Sep 2020 13:36'	(b) (4), (b) (6) System	24 Sep 2020 18:36:56
	System	24 Sep 2020 18:36:56

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Sep 2020 12:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 2'	System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:16:59', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5365871b-85d7-43b0-9344-3a624b412253'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	26 Sep 2020 05:17:16

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:06', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5365871b-85d7-43b0-9344-3a624b412253' User entered '97.7'	(b) (4), (b) (6) System	26 Sep 2020 05:17:16
	System	26 Sep 2020 05:17:16

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:09', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5365871b-85d7-43b0-9344-3a624b412253' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 05:17:16
	System	26 Sep 2020 05:17:16

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:12', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5365871b-85d7-43b0-9344-3a624b412253' User entered '26 Sep 2020 00:17'	(b) (4), (b) (6) System	26 Sep 2020 05:17:16
	System	26 Sep 2020 05:17:16

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 3'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:44:44', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e74647b1-c715-453d-96b6-1fbf581f16a9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:44:50', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e74647b1-c715-453d-96b6-1fbf581f16a9' User entered '97.8'	(b) (4), (b) (6) System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:44:55', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e74647b1-c715-453d-96b6-1fbf581f16a9' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:44:57', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e74647b1-c715-453d-96b6-1fbf581f16a9' User entered '26 Sep 2020 15:44'	(b) (4), (b) (6) System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 4'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:03:40', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e2b8089e-8316-4c20-827b-0f6104a77993' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Sep 2020 00:03:54
	System	28 Sep 2020 00:03:54

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:03:46', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e2b8089e-8316-4c20-827b-0f6104a77993' User entered '96.6'	(b) (4), (b) (6) System	28 Sep 2020 00:03:54
	System	28 Sep 2020 00:03:54

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:03:49', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e2b8089e-8316-4c20-827b-0f6104a77993' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:03:54
	System	28 Sep 2020 00:03:54

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:03:51', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e2b8089e-8316-4c20-827b-0f6104a77993' User entered '27 Sep 2020 19:03'	(b) (4), (b) (6) System	28 Sep 2020 00:03:54
	System	28 Sep 2020 00:03:54

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 5'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:25', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd213623e-d841-4d02-8a58-419eeda4532b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Sep 2020 17:00:44
	System	28 Sep 2020 17:00:44

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:31', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd213623e-d841-4d02-8a58-419eeda4532b' User entered '97.0'	(b) (4), (b) (6) System	28 Sep 2020 17:00:44
	System	28 Sep 2020 17:00:44

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd213623e-d841-4d02-8a58-419eeda4532b' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 17:00:44
	System	28 Sep 2020 17:00:44

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:36', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd213623e-d841-4d02-8a58-419eeda4532b' User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 17:00:44
	System	28 Sep 2020 17:00:44

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 6'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:06:42', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '6a0e06e5-1e86-4262-88a7-b2428a24e884' User entered 'Yes (Y)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:16
	System	30 Sep 2020 05:07:16

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:10', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '6a0e06e5-1e86-4262-88a7-b2428a24e884' User entered '98.0'	(b) (4), (b) (6) System	30 Sep 2020 05:07:16
	System	30 Sep 2020 05:07:16

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:12', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '6a0e06e5-1e86-4262-88a7-b2428a24e884' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:16
	System	30 Sep 2020 05:07:16

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:15', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '6a0e06e5-1e86-4262-88a7-b2428a24e884' User entered '30 Sep 2020 00:07'	(b) (4), (b) (6) System	30 Sep 2020 05:07:16
	System	30 Sep 2020 05:07:16

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 7'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:59:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:54:30', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '281825d0-dd70-4f46-8d9f-2a530ba08dba' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 14:54:55
	System	24 Sep 2020 14:54:55

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:54:37', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '281825d0-dd70-4f46-8d9f-2a530ba08dba' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 14:54:55
	System	24 Sep 2020 14:54:55

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:54:44', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '281825d0-dd70-4f46-8d9f-2a530ba08dba' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 14:54:55
	System	24 Sep 2020 14:54:55

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:54:49', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '281825d0-dd70-4f46-8d9f-2a530ba08dba' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 14:54:55
	System	24 Sep 2020 14:54:55

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:54:53', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '281825d0-dd70-4f46-8d9f-2a530ba08dba' User entered '24 Sep 2020 09:54'	(b) (4), (b) (6) System	24 Sep 2020 14:54:55
	System	24 Sep 2020 14:54:55

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Sep 2020 09:34'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Sep 2020 12:04'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:37:16', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'fce687d5-0460-4883-96b5-6dcb516aecb7' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 18:37:57
	System	24 Sep 2020 18:37:57

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:37:25', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'fce687d5-0460-4883-96b5-6dcb516aeb7' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 18:37:57
	System	24 Sep 2020 18:37:57

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:37:39', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'fce687d5-0460-4883-96b5-6dcb516aeb7' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 18:37:57
	System	24 Sep 2020 18:37:57

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:37:46', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'fce687d5-0460-4883-96b5-6dcb516aecb7' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 18:37:57
	System	24 Sep 2020 18:37:57

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:37:56', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'fce687d5-0460-4883-96b5-6dcb516aecb7' User entered '24 Sep 2020 13:37'	(b) (4), (b) (6) System	24 Sep 2020 18:37:57
	System	24 Sep 2020 18:37:57

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Sep 2020 12:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 2'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:17', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '15fff780-69de-48df-8003-632c6b3e9dd6'	(b) (4), (b) (6)	
	System	26 Sep 2020 05:17:31
User entered 'None (1)'	System	26 Sep 2020 05:17:31

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:19', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '15fff780-69de-48df-8003-632c6b3e9dd6' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 05:17:31
	System	26 Sep 2020 05:17:31

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:21', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '15fff780-69de-48df-8003-632c6b3e9dd6'	(b) (4), (b) (6)	
	System	26 Sep 2020 05:17:31
User entered 'No (N)'	System	26 Sep 2020 05:17:31

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:24', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '15fff780-69de-48df-8003-632c6b3e9dd6'	(b) (4), (b) (6)	
	System	26 Sep 2020 05:17:31
User entered 'None (1)'	System	26 Sep 2020 05:17:31

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:27', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '15fff780-69de-48df-8003-632c6b3e9dd6' User entered '26 Sep 2020 00:17'	(b) (4), (b) (6) System	26 Sep 2020 05:17:31
	System	26 Sep 2020 05:17:31

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 3'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:08', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a3afb378-1bf6-484a-80c9-5dd0610936d5' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:28
	System	26 Sep 2020 20:45:28

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:15', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a3afb378-1bf6-484a-80c9-5dd0610936d5' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:28
	System	26 Sep 2020 20:45:28

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:17', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a3afb378-1bf6-484a-80c9-5dd0610936d5' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:28
	System	26 Sep 2020 20:45:28

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:20', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a3afb378-1bf6-484a-80c9-5dd0610936d5' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:28
	System	26 Sep 2020 20:45:28

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:23', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'a3afb378-1bf6-484a-80c9-5dd0610936d5' User entered '26 Sep 2020 15:45'	(b) (4), (b) (6) System	26 Sep 2020 20:45:28
	System	26 Sep 2020 20:45:28

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 4'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:03:56', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '614a21ff-0db8-4c43-9acf-9b026f3831c6' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:15
	System	28 Sep 2020 00:04:15

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:03:59', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '614a21ff-0db8-4c43-9acf-9b026f3831c6' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:15
	System	28 Sep 2020 00:04:15

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:09', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '614a21ff-0db8-4c43-9acf-9b026f3831c6' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:15
	System	28 Sep 2020 00:04:15

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:11', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '614a21ff-0db8-4c43-9acf-9b026f3831c6' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:15
	System	28 Sep 2020 00:04:15

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:14', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '614a21ff-0db8-4c43-9acf-9b026f3831c6' User entered '27 Sep 2020 19:04'	(b) (4), (b) (6) System	28 Sep 2020 00:04:15
	System	28 Sep 2020 00:04:15

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 5'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:43', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f342841d-4688-4e62-8374-3d3f909fca86' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:16
	System	28 Sep 2020 17:01:16

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:46', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f342841d-4688-4e62-8374-3d3f909fca86' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:16
	System	28 Sep 2020 17:01:16

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:48', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f342841d-4688-4e62-8374-3d3f909fca86' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:16
	System	28 Sep 2020 17:01:16

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:50', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f342841d-4688-4e62-8374-3d3f909fca86'	(b) (4), (b) (6) System	28 Sep 2020 17:01:16
User entered 'None (1)'	System	28 Sep 2020 17:01:16

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:52', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f342841d-4688-4e62-8374-3d3f909fca86' User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 17:01:16
	System	28 Sep 2020 17:01:16

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 6'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:18', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '7b4e49ee-0384-4b8e-9a89-9bba42f9014c' User entered 'None (1)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:28
	System	30 Sep 2020 05:07:28

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:20', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '7b4e49ee-0384-4b8e-9a89-9bba42f9014c' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:28
	System	30 Sep 2020 05:07:28

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:22', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '7b4e49ee-0384-4b8e-9a89-9bba42f9014c' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:28
	System	30 Sep 2020 05:07:28

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:24', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '7b4e49ee-0384-4b8e-9a89-9bba42f9014c' User entered 'None (1)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:28
	System	30 Sep 2020 05:07:28

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:26', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '7b4e49ee-0384-4b8e-9a89-9bba42f9014c' User entered '30 Sep 2020 00:07'	(b) (4), (b) (6) System	30 Sep 2020 05:07:28
	System	30 Sep 2020 05:07:28

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 7'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:55:07', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3d292f37-6b13-4fa6-8083-66d22a279ed3' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:55:53
	System	24 Sep 2020 14:55:53

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:55:30', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3d292f37-6b13-4fa6-8083-66d22a279ed3' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:55:53
	System	24 Sep 2020 14:55:53

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:55:34', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3d292f37-6b13-4fa6-8083-66d22a279ed3' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:55:53
	System	24 Sep 2020 14:55:53

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:55:38', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3d292f37-6b13-4fa6-8083-66d22a279ed3' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:55:53
	System	24 Sep 2020 14:55:53

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:55:41', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3d292f37-6b13-4fa6-8083-66d22a279ed3' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:55:53
	System	24 Sep 2020 14:55:53

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:55:44', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3d292f37-6b13-4fa6-8083-66d22a279ed3' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:55:53
	System	24 Sep 2020 14:55:53

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:55:48', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3d292f37-6b13-4fa6-8083-66d22a279ed3' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 14:55:53
	System	24 Sep 2020 14:55:53

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:59:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T09:55:51', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '3d292f37-6b13-4fa6-8083-66d22a279ed3' User entered '24 Sep 2020 09:55'	(b) (4), (b) (6) System	24 Sep 2020 14:55:53
	System	24 Sep 2020 14:55:53

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Sep 2020 09:34'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Sep 2020 12:04'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:38:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '181f757c-5655-4b26-b744-a4bb8f5720ea' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:19
	System	24 Sep 2020 18:38:19

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:38:03', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '181f757c-5655-4b26-b744-a4bb8f5720ea' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:19
	System	24 Sep 2020 18:38:19

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:38:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '181f757c-5655-4b26-b744-a4bb8f5720ea' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:19
	System	24 Sep 2020 18:38:19

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:38:08', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '181f757c-5655-4b26-b744-a4bb8f5720ea' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:19
	System	24 Sep 2020 18:38:19

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:38:10', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '181f757c-5655-4b26-b744-a4bb8f5720ea' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:19
	System	24 Sep 2020 18:38:19

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:38:12', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '181f757c-5655-4b26-b744-a4bb8f5720ea' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:19
	System	24 Sep 2020 18:38:19

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:38:15', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '181f757c-5655-4b26-b744-a4bb8f5720ea' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 18:38:19
	System	24 Sep 2020 18:38:19

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-24T13:38:18', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '181f757c-5655-4b26-b744-a4bb8f5720ea' User entered '24 Sep 2020 13:38'	(b) (4), (b) (6) System	24 Sep 2020 18:38:19
	System	24 Sep 2020 18:38:19

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '24 Sep 2020 12:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 2'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:31', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ad4e78ef-4b77-4258-a81a-346871804541' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:17:47
	System	26 Sep 2020 05:17:47

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ad4e78ef-4b77-4258-a81a-346871804541' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:17:47
	System	26 Sep 2020 05:17:47

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:35', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ad4e78ef-4b77-4258-a81a-346871804541' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:17:47
	System	26 Sep 2020 05:17:47

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:37', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ad4e78ef-4b77-4258-a81a-346871804541' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:17:47
	System	26 Sep 2020 05:17:47

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:39', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ad4e78ef-4b77-4258-a81a-346871804541' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:17:47
	System	26 Sep 2020 05:17:47

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:41', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ad4e78ef-4b77-4258-a81a-346871804541' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 05:17:47
	System	26 Sep 2020 05:17:47

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:44', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ad4e78ef-4b77-4258-a81a-346871804541' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 05:17:47
	System	26 Sep 2020 05:17:47

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T00:17:46', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'ad4e78ef-4b77-4258-a81a-346871804541' User entered '26 Sep 2020 00:17'	(b) (4), (b) (6) System	26 Sep 2020 05:17:47
	System	26 Sep 2020 05:17:47

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 3'	System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:28', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '30e65918-7b7e-4f2b-9605-e13c200b26a6' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:50
	System	26 Sep 2020 20:45:50

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:30', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '30e65918-7b7e-4f2b-9605-e13c200b26a6' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:50
	System	26 Sep 2020 20:45:50

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '30e65918-7b7e-4f2b-9605-e13c200b26a6' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:50
	System	26 Sep 2020 20:45:50

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:35', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '30e65918-7b7e-4f2b-9605-e13c200b26a6' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:50
	System	26 Sep 2020 20:45:50

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:38', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '30e65918-7b7e-4f2b-9605-e13c200b26a6' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:50
	System	26 Sep 2020 20:45:50

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:41', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '30e65918-7b7e-4f2b-9605-e13c200b26a6' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:50
	System	26 Sep 2020 20:45:50

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:45', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '30e65918-7b7e-4f2b-9605-e13c200b26a6' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 20:45:50
	System	26 Sep 2020 20:45:50

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-26T15:45:47', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '30e65918-7b7e-4f2b-9605-e13c200b26a6' User entered '26 Sep 2020 15:45'	(b) (4), (b) (6) System	26 Sep 2020 20:45:50
	System	26 Sep 2020 20:45:50

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 4'	System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:17', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bb723a8d-2c8e-49f8-b21a-a2b4965743b3' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:35
	System	28 Sep 2020 00:04:35

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:19', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bb723a8d-2c8e-49f8-b21a-a2b4965743b3' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:35
	System	28 Sep 2020 00:04:35

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:21', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bb723a8d-2c8e-49f8-b21a-a2b4965743b3' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:35
	System	28 Sep 2020 00:04:35

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:23', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bb723a8d-2c8e-49f8-b21a-a2b4965743b3' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:35
	System	28 Sep 2020 00:04:35

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:25', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bb723a8d-2c8e-49f8-b21a-a2b4965743b3' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:35
	System	28 Sep 2020 00:04:35

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:27', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bb723a8d-2c8e-49f8-b21a-a2b4965743b3' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:35
	System	28 Sep 2020 00:04:35

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:29', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bb723a8d-2c8e-49f8-b21a-a2b4965743b3' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 00:04:35
	System	28 Sep 2020 00:04:35

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-27T19:04:32', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bb723a8d-2c8e-49f8-b21a-a2b4965743b3' User entered '27 Sep 2020 19:04'	(b) (4), (b) (6) System	28 Sep 2020 00:04:35
	System	28 Sep 2020 00:04:35

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 5'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:55', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd8bdfa13-2c28-4eec-b6d5-4f0f03378699' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:40
	System	28 Sep 2020 17:01:40

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:57', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd8bdfa13-2c28-4eec-b6d5-4f0f03378699' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:40
	System	28 Sep 2020 17:01:40

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:00:58', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd8bdfa13-2c28-4eec-b6d5-4f0f03378699' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:40
	System	28 Sep 2020 17:01:40

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:01:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd8bdfa13-2c28-4eec-b6d5-4f0f03378699' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:40
	System	28 Sep 2020 17:01:40

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:01:01', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd8bdfa13-2c28-4eec-b6d5-4f0f03378699' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:40
	System	28 Sep 2020 17:01:40

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:01:03', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd8bdfa13-2c28-4eec-b6d5-4f0f03378699' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:40
	System	28 Sep 2020 17:01:40

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:01:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd8bdfa13-2c28-4eec-b6d5-4f0f03378699' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 17:01:40
	System	28 Sep 2020 17:01:40

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-28T12:01:08', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd8bdfa13-2c28-4eec-b6d5-4f0f03378699' User entered '28 Sep 2020 12:01'	(b) (4), (b) (6) System	28 Sep 2020 17:01:40
	System	28 Sep 2020 17:01:40

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 6'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:30', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0d3e6816-40ff-4da7-81c8-cb253d8a0914' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:45
	System	30 Sep 2020 05:07:45

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:31', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0d3e6816-40ff-4da7-81c8-cb253d8a0914' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:45
	System	30 Sep 2020 05:07:45

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:33', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0d3e6816-40ff-4da7-81c8-cb253d8a0914' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:45
	System	30 Sep 2020 05:07:45

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:35', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0d3e6816-40ff-4da7-81c8-cb253d8a0914' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:45
	System	30 Sep 2020 05:07:45

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:36', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0d3e6816-40ff-4da7-81c8-cb253d8a0914' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:45
	System	30 Sep 2020 05:07:45

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:38', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0d3e6816-40ff-4da7-81c8-cb253d8a0914' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:45
	System	30 Sep 2020 05:07:45

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:40', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0d3e6816-40ff-4da7-81c8-cb253d8a0914' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 05:07:45
	System	30 Sep 2020 05:07:45

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-09-30T00:07:42', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '0d3e6816-40ff-4da7-81c8-cb253d8a0914' User entered '30 Sep 2020 00:07'	(b) (4), (b) (6) System	30 Sep 2020 05:07:45
	System	30 Sep 2020 05:07:45

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:53:11
User entered 'Day 7'	System	24 Sep 2020 14:53:11

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

US3042309

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:59:37

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) (b) (4), (b) (6)	25 Feb 2021 04:59:52

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 04:59:52

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:59:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:53:11

**US3042309**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:00
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	01 Oct 2020 15:13:01
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:00
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '01 Oct 2020'	Rylea Gulick (b) (4)	01 Oct 2020 15:13:01
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:00
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	01 Oct 2020 15:13:01
	(b) (4)	

US3042309

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:00
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	01 Oct 2020 15:13:01
	(b) (4)	

US3042309

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:00
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	01 Oct 2020 15:13:02
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:00
User entered 'I'	(b) (4), (b) (6) System	01 Oct 2020 15:13:02

**US3042309**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:24:07
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	08 Oct 2020 18:06:21
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:24:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '08 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 18:06:21

**US3042309**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:24:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 18:06:21

**US3042309**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:24:07
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	08 Oct 2020 18:06:21
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:24:07
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	08 Oct 2020 18:06:24
	(b) (4)	

**US3042309**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:24:07
User entered 'I'	(b) (4), (b) (6) System	08 Oct 2020 18:06:24

**US3042309**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 02:01:46
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Oct 2020 16:27:00

**US3042309**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 02:01:46
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 22:00:08
User entered '15 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	15 Oct 2020 16:27:00

**US3042309**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 02:01:46
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 22:00:08
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	15 Oct 2020 16:27:00

US3042309

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:01:46
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Oct 2020 16:27:00
	(b) (4)	

US3042309

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 02:01:46
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Oct 2020 16:27:02

**US3042309**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:01:46
	(b) (4), (b) (6)	
User entered '1'	System	15 Oct 2020 16:27:02

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:42:50

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:10
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 15:42:54
User entered '22 Oct 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	22 Oct 2020 15:42:54
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Oct 2020 15:42:50
User entered '23 Oct 2020'	Rylea Gulick (b) (4)	22 Oct 2020 15:42:50
	(b) (4)	

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:42:50

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User entered 'VISIT3'	(b) (4), (b) (6) System	22 Oct 2020 15:42:50

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:04

US3042309

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:37

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:10
	(b) (4)	
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Oct 2020 15:43:10
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	22 Oct 2020 15:43:10
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	22 Oct 2020 15:43:10
User entered '22 Oct 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	22 Oct 2020 15:43:10
	(b) (4)	
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Oct 2020 15:43:04
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	22 Oct 2020 15:43:04
User entered '22 Oct 2002'	Rylea Gulick (b) (4)	22 Oct 2020 15:43:04
	(b) (4)	

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '08:02'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User entered '22 Oct 2020 08:02'	(b) (4), (b) (6)	
	System	22 Oct 2020 15:43:10
User entered '22 Oct 2002 08:02'	System	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:10
	(b) (4)	
User entered '36.8' C	Rylea Gulick (b) (4)	22 Oct 2020 15:43:04
	(b) (4)	

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:10
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	22 Oct 2020 15:43:04
	(b) (4)	

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '76'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User entered 'bpm'	(b) (4), (b) (6) System	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '124'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User entered 'mmHg'	(b) (4), (b) (6) System	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User entered 'mmHg'	(b) (4), (b) (6) System	22 Oct 2020 15:43:04

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:48

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:48

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:15

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '22 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:15

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:25

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '22 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:25

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:10
	(b) (4)	
User entered '08:15'	Rylea Gulick (b) (4)	22 Oct 2020 15:43:25
	(b) (4)	

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User entered '22 Oct 2020 08:15'	(b) (4), (b) (6) System	22 Oct 2020 15:43:25

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	22 Oct 2020 15:43:27

**US3042309**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:48
User entered '1'	(b) (4), (b) (6) System	22 Oct 2020 15:43:27

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 64'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-10-22T17:10:28', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e44b3fb1-641b-46fb-9e38-7d69f1e50e9f' User entered 'No (N)'	(b) (4), (b) (6) System	22 Oct 2020 22:11:15
	System	22 Oct 2020 22:11:15

US3042309

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-10-22T17:10:49', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e44b3fb1-641b-46fb-9e38-7d69f1e50e9f' User entered 'No (N)'	(b) (4), (b) (6) System	22 Oct 2020 22:11:15
	System	22 Oct 2020 22:11:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-10-22T17:11:14', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e44b3fb1-641b-46fb-9e38-7d69f1e50e9f' User entered '22 Oct 2020 17:11:14'	(b) (4), (b) (6) System	22 Oct 2020 22:11:15
	System	22 Oct 2020 22:11:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 71'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-10-29T13:27:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5ecad251-e189-4187-8fc3-3e886bd833d0'	(b) (4), (b) (6)	
	System	29 Oct 2020 18:27:19
User entered 'No (N)'	System	29 Oct 2020 18:27:19

US3042309

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-10-29T13:27:12', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5ecad251-e189-4187-8fc3-3e886bd833d0'	(b) (4), (b) (6)	
	System	29 Oct 2020 18:27:19
User entered 'No (N)'	System	29 Oct 2020 18:27:19

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-10-29T13:27:15', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '5ecad251-e189-4187-8fc3-3e886bd833d0' User entered '29 Oct 2020 13:27:15'	(b) (4), (b) (6) System	29 Oct 2020 18:27:19
	System	29 Oct 2020 18:27:19

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 78'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-11-05T10:05:06', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '63c0605b-b617-4a40-8933-f9deea2e3008' User entered 'No (N)'	(b) (4), (b) (6) System	05 Nov 2020 16:05:21
	System	05 Nov 2020 16:05:21

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-11-05T10:05:12', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '63c0605b-b617-4a40-8933-f9deea2e3008'	(b) (4), (b) (6)	
User entered 'No (N)'	System	05 Nov 2020 16:05:21

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-11-05T10:05:16', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '63c0605b-b617-4a40-8933-f9deea2e3008' User entered '05 Nov 2020 10:05:16'	(b) (4), (b) (6) System	05 Nov 2020 16:05:21
	System	05 Nov 2020 16:05:21

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered 'Day 92'	System	22 Aug 2020 19:50:31

US3042309

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-11-19T07:20:57', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c3ad3ce6-2508-4692-8b03-2a60e606ae43' User entered 'No (N)'	(b) (4), (b) (6) System	19 Nov 2020 13:21:29
	System	19 Nov 2020 13:21:29

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-11-19T07:21:08', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c3ad3ce6-2508-4692-8b03-2a60e606ae43' User entered 'No (N)'	(b) (4), (b) (6) System	19 Nov 2020 13:21:29
	System	19 Nov 2020 13:21:29

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-11-19T07:21:26', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c3ad3ce6-2508-4692-8b03-2a60e606ae43' User entered '19 Nov 2020 07:21:26'	(b) (4), (b) (6) System	19 Nov 2020 13:21:29
	System	19 Nov 2020 13:21:29

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:59:52
	(b) (4), (b) (6)	
Data entry locked.	System	22 Aug 2020 19:50:31
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 19:50:31

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-11-26T00:22:11', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '538b3afb-e03a-4280-99cc-f2c0e85293b8'	System	26 Nov 2020 06:22:27
User entered 'No (N)'	System	26 Nov 2020 06:22:27

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-11-26T00:22:21', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '538b3afb-e03a-4280-99cc-f2c0e85293b8' User entered 'No (N)'	System	26 Nov 2020 06:22:27

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-11-26T00:22:24', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '538b3afb-e03a-4280-99cc-f2c0e85293b8' User entered '26 Nov 2020 00:22:24'	System	26 Nov 2020 06:22:27
	System	26 Nov 2020 06:22:27

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-01T15:35:24', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '6a7f7e4b-bebc-4f72-b611-9891678a630c' User entered 'No (N)'	System	01 Dec 2020 21:35:37

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-01T15:35:28', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '6a7f7e4b-bebc-4f72-b611-9891678a630c' User entered 'No (N)'	System	01 Dec 2020 21:35:37

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-01T15:35:31', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '6a7f7e4b-bebc-4f72-b611-9891678a630c' User entered '01 Dec 2020 15:35:31'	System	01 Dec 2020 21:35:37
	System	01 Dec 2020 21:35:37

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-07T16:10:44', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '79fe191e-213a-4922-844c-8520baef64d6'	System	07 Dec 2020 22:10:58
User entered 'No (N)'	System	07 Dec 2020 22:10:58

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-07T16:10:52', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '79fe191e-213a-4922-844c-8520baef64d6'	System	07 Dec 2020 22:10:58
User entered 'No (N)'	System	07 Dec 2020 22:10:58

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-07T16:10:55', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '79fe191e-213a-4922-844c-8520baef64d6' User entered '07 Dec 2020 16:10:55'	System	07 Dec 2020 22:10:58
	System	07 Dec 2020 22:10:58

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-15T17:47:47', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '05a88838-cd4e-4795-bf19-0f530f4e79a4'	System	15 Dec 2020 23:47:57
User entered 'No (N)'	System	15 Dec 2020 23:47:57

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-15T17:47:51', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '05a88838-cd4e-4795-bf19-0f530f4e79a4'	System	15 Dec 2020 23:47:57
User entered 'No (N)'	System	15 Dec 2020 23:47:57

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-15T17:47:54', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '05a88838-cd4e-4795-bf19-0f530f4e79a4' User entered '15 Dec 2020 17:47:54'	System	15 Dec 2020 23:47:57
	System	15 Dec 2020 23:47:57

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-21T11:13:07', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f43eea33-8210-4d55-a6fe-cda3677174c9' User entered 'No (N)'	System	21 Dec 2020 17:15:35
	System	21 Dec 2020 17:15:35

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-21T11:13:14', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f43eea33-8210-4d55-a6fe-cda3677174c9'	System	21 Dec 2020 17:15:35
User entered 'No (N)'	System	21 Dec 2020 17:15:35

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-21T11:15:31', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f43eea33-8210-4d55-a6fe-cda3677174c9' User entered '21 Dec 2020 11:15:31'	System	21 Dec 2020 17:15:35
	System	21 Dec 2020 17:15:35

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-28T00:48:29', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f996f8f9-caf6-4215-bcb8-00134274e56e' User entered 'No (N)'	System	28 Dec 2020 06:48:42
	System	28 Dec 2020 06:48:42

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-28T00:48:25', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f996f8f9-caf6-4215-bcb8-00134274e56e' User entered 'No (N)'	System	28 Dec 2020 06:48:42
	System	28 Dec 2020 06:48:42

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2020-12-28T00:48:38', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f996f8f9-caf6-4215-bcb8-00134274e56e' User entered '28 Dec 2020 00:48:38'	System	28 Dec 2020 06:48:42
	System	28 Dec 2020 06:48:42

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-04T00:28:04', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd16c8378-96b2-45c1-8bec-b74b65bf12d8'	System	04 Jan 2021 06:28:23
User entered 'No (N)'	System	04 Jan 2021 06:28:23

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-04T00:28:17', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd16c8378-96b2-45c1-8bec-b74b65bf12d8'	System	04 Jan 2021 06:28:23
User entered 'No (N)'	System	04 Jan 2021 06:28:23

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-04T00:28:21', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'd16c8378-96b2-45c1-8bec-b74b65bf12d8' User entered '04 Jan 2021 00:28:21'	System	04 Jan 2021 06:28:23
	System	04 Jan 2021 06:28:23

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-11T00:01:24', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e67e6231-8bab-4f47-b25b-3569ae507cc7'	System	11 Jan 2021 06:01:48
User entered 'No (N)'	System	11 Jan 2021 06:01:48

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-11T00:01:28', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e67e6231-8bab-4f47-b25b-3569ae507cc7'	System	11 Jan 2021 06:01:48
User entered 'No (N)'	System	11 Jan 2021 06:01:48

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-11T00:01:36', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'e67e6231-8bab-4f47-b25b-3569ae507cc7' User entered '11 Jan 2021 00:01:36'	System	11 Jan 2021 06:01:48
	System	11 Jan 2021 06:01:48

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-18T00:31:48', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '52824cfd-0a0a-4f1c-984d-38cc86b787b4'	System	18 Jan 2021 06:32:03
User entered 'No (N)'	System	18 Jan 2021 06:32:03

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-18T00:31:55', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '52824cfd-0a0a-4f1c-984d-38cc86b787b4'	System	18 Jan 2021 06:32:03
User entered 'No (N)'	System	18 Jan 2021 06:32:03

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-18T00:31:59', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '52824cfd-0a0a-4f1c-984d-38cc86b787b4' User entered '18 Jan 2021 00:31:59'	System	18 Jan 2021 06:32:03
	System	18 Jan 2021 06:32:03

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-25T06:20:53', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '66d066fd-9323-4f57-94d3-6ee88102a1ef'	System	25 Jan 2021 12:21:05
User entered 'No (N)'	System	25 Jan 2021 12:21:05

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-25T06:20:58', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '66d066fd-9323-4f57-94d3-6ee88102a1ef'	System	25 Jan 2021 12:21:05
User entered 'No (N)'	System	25 Jan 2021 12:21:05

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-01-25T06:21:02', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '66d066fd-9323-4f57-94d3-6ee88102a1ef' User entered '25 Jan 2021 06:21:02'	System	25 Jan 2021 12:21:05
	System	25 Jan 2021 12:21:05

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-01T12:08:01', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bc9d0a0a-8d42-4919-bc58-0ba604e36323' User entered 'No (N)'	System	01 Feb 2021 18:08:22
	System	01 Feb 2021 18:08:22

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-01T12:08:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bc9d0a0a-8d42-4919-bc58-0ba604e36323' User entered 'No (N)'	System	01 Feb 2021 18:08:22
	System	01 Feb 2021 18:08:22

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-01T12:08:08', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'bc9d0a0a-8d42-4919-bc58-0ba604e36323' User entered '01 Feb 2021 12:08:08'	System	01 Feb 2021 18:08:22
	System	01 Feb 2021 18:08:22

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-08T11:25:45', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'df063459-71fc-4775-9df3-4d006d4c1cad' User entered 'No (N)'	System	08 Feb 2021 17:25:55
	System	08 Feb 2021 17:25:55

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-08T11:25:48', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'df063459-71fc-4775-9df3-4d006d4c1cad' User entered 'No (N)'	System	08 Feb 2021 17:25:55
	System	08 Feb 2021 17:25:55

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-08T11:25:53', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'df063459-71fc-4775-9df3-4d006d4c1cad' User entered '08 Feb 2021 11:25:53'	System	08 Feb 2021 17:25:55
	System	08 Feb 2021 17:25:55

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-17T08:36:41', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '36e7481e-bead-4d57-8813-cf7eb66b203b' User entered 'Yes (Y)'	System	17 Feb 2021 14:37:22
	System	17 Feb 2021 14:37:22

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-17T08:36:46', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '36e7481e-bead-4d57-8813-cf7eb66b203b' User entered 'No (N)'	System	17 Feb 2021 14:37:22
	System	17 Feb 2021 14:37:22

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-17T08:36:49', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '36e7481e-bead-4d57-8813-cf7eb66b203b' User entered 'No (N)'	System	17 Feb 2021 14:37:22
	System	17 Feb 2021 14:37:22

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-17T08:37:05', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '36e7481e-bead-4d57-8813-cf7eb66b203b' User entered 'Yes (Y)'	System	17 Feb 2021 14:37:22
	System	17 Feb 2021 14:37:22

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Please 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-17T08:37:10', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '36e7481e-bead-4d57-8813-cf7eb66b203b'	System	17 Feb 2021 14:37:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Feb 2021 14:37:22

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-17T08:37:13', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '36e7481e-bead-4d57-8813-cf7eb66b203b' User entered '17 Feb 2021 08:37:13'	System	17 Feb 2021 14:37:22
	System	17 Feb 2021 14:37:22

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-22T15:20:58-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '1305987e-f91a-422d-aaa6-d03f0956667a' User entered 'No (N)'	System	22 Feb 2021 21:21:09
	System	22 Feb 2021 21:21:09

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-22T15:21:01-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '1305987e-f91a-422d-aaa6-d03f0956667a' User entered 'No (N)'	System	22 Feb 2021 21:21:09

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-02-22T15:21:04-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '1305987e-f91a-422d-aaa6-d03f0956667a' User entered '22 Feb 2021 21:21:04'	System	22 Feb 2021 21:21:09
	System	22 Feb 2021 21:21:09

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-01T00:04:14-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'da4f8d74-9d0c-4ed6-a6f6-9ab146998950'	System	05 Mar 2021 18:18:21
User entered 'No (N)'	System	05 Mar 2021 18:18:21

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-01T00:04:21-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'da4f8d74-9d0c-4ed6-a6f6-9ab146998950'	System	05 Mar 2021 18:18:21
User entered 'No (N)'	System	05 Mar 2021 18:18:21

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-01T00:04:26-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'da4f8d74-9d0c-4ed6-a6f6-9ab146998950'	System	05 Mar 2021 18:18:21
User entered '01 Mar 2021 00:04:26'	System	05 Mar 2021 18:18:21

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-08T11:55:05-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '836d8412-da95-4858-9e58-f7f186d88df4'	System	08 Mar 2021 17:55:18
User entered 'No (N)'	System	08 Mar 2021 17:55:18

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-08T11:55:09-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '836d8412-da95-4858-9e58-f7f186d88df4'	System	08 Mar 2021 17:55:18
User entered 'No (N)'	System	08 Mar 2021 17:55:18

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-08T11:55:13-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '836d8412-da95-4858-9e58-f7f186d88df4'	System	08 Mar 2021 17:55:18
User entered '08 Mar 2021 11:55:13'	System	08 Mar 2021 17:55:18

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-15T19:16:33-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '53476d2c-64f6-40fa-8b3a-b10ff0bebcae'	System	16 Mar 2021 00:16:42
User entered 'No (N)'	System	16 Mar 2021 00:16:42

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-15T19:16:36-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '53476d2c-64f6-40fa-8b3a-b10ff0bebcae'	System	16 Mar 2021 00:16:42
User entered 'No (N)'	System	16 Mar 2021 00:16:42

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-15T19:16:39-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '53476d2c-64f6-40fa-8b3a-b10ff0bebcae' User entered '15 Mar 2021 19:16:39'	System	16 Mar 2021 00:16:42
	System	16 Mar 2021 00:16:42

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-22T00:02:22-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '4823af66-f242-484d-a75a-f81d7dcba15c'	System	22 Mar 2021 05:02:34
User entered 'No (N)'	System	22 Mar 2021 05:02:34

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-22T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '4823af66-f242-484d-a75a-f81d7dcba15c'	System	22 Mar 2021 05:02:34
User entered 'No (N)'	System	22 Mar 2021 05:02:34

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-22T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '4823af66-f242-484d-a75a-f81d7dcba15c' User entered '22 Mar 2021 00:02:31'	System	22 Mar 2021 05:02:34
	System	22 Mar 2021 05:02:34

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-29T00:02:27-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8da8adb0-b330-4597-9410-09e0dc5b61d8'	System	29 Mar 2021 05:02:38
User entered 'No (N)'	System	29 Mar 2021 05:02:38

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-29T00:02:33-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8da8adb0-b330-4597-9410-09e0dc5b61d8'	System	29 Mar 2021 05:02:38
User entered 'No (N)'	System	29 Mar 2021 05:02:38

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-29T00:02:36-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '8da8adb0-b330-4597-9410-09e0dc5b61d8'	System	29 Mar 2021 05:02:38
User entered '29 Mar 2021 00:02:36'	System	29 Mar 2021 05:02:38

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-05T09:40:36-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f1f7f0f1-4494-41c3-a5a6-0030b37c5811' User entered 'No (N)'	System	05 Apr 2021 14:40:47
	System	05 Apr 2021 14:40:47

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-05T09:40:41-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f1f7f0f1-4494-41c3-a5a6-0030b37c5811'	System	05 Apr 2021 14:40:47
User entered 'No (N)'	System	05 Apr 2021 14:40:47

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-05T09:40:43-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'f1f7f0f1-4494-41c3-a5a6-0030b37c5811' User entered '05 Apr 2021 09:40:43'	System	05 Apr 2021 14:40:47
	System	05 Apr 2021 14:40:47

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-12T19:38:18-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c5d30e62-eb4b-4c5d-954c-bf28c217ff7a' User entered 'No (N)'	System	13 Apr 2021 00:38:28
	System	13 Apr 2021 00:38:28

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-12T19:38:21-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c5d30e62-eb4b-4c5d-954c-bf28c217ff7a'	System	13 Apr 2021 00:38:28
User entered 'No (N)'	System	13 Apr 2021 00:38:28

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-12T19:38:24-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: 'c5d30e62-eb4b-4c5d-954c-bf28c217ff7a'	System	13 Apr 2021 00:38:28
User entered '12 Apr 2021 19:38:24'	System	13 Apr 2021 00:38:28

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-19T00:04:01-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '433bd994-77e7-4825-bdef-fcdf48eea50f' User entered 'No (N)'	System	19 Apr 2021 05:04:34

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-19T00:04:07-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '433bd994-77e7-4825-bdef-fcdf48eea50f' User entered 'Yes (Y)'	System	19 Apr 2021 05:04:34
	System	19 Apr 2021 05:04:34

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Please 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-19T00:04:19-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '433bd994-77e7-4825-bdef-fcdf48eea50f'	System	19 Apr 2021 05:04:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Apr 2021 05:04:34

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-19T00:04:23-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '433bd994-77e7-4825-bdef-fcdf48eea50f' User entered '19 Apr 2021 00:04:23'	System	19 Apr 2021 05:04:34
	System	19 Apr 2021 05:04:34

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-26T13:08:43-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '86e6eab4-d9fd-40db-824b-97cd7bd2c287'	System	26 Apr 2021 18:09:13
User entered 'No (N)'	System	26 Apr 2021 18:09:13

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-26T13:08:46-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '86e6eab4-d9fd-40db-824b-97cd7bd2c287'	System	26 Apr 2021 18:09:13
User entered 'No (N)'	System	26 Apr 2021 18:09:13

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-04-26T13:08:49-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '86e6eab4-d9fd-40db-824b-97cd7bd2c287'	System	26 Apr 2021 18:09:13
User entered '26 Apr 2021 13:08:49'	System	26 Apr 2021 18:09:13

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-05-03T01:59:48-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '978c3077-75c5-4600-afe6-caa7e155db64'	System	03 May 2021 06:59:55
User entered 'No (N)'	System	03 May 2021 06:59:55

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

Have you been exposed to someone with 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 (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-05-03T01:59:50-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '978c3077-75c5-4600-afe6-caa7e155db64'	System	03 May 2021 06:59:55
User entered 'No (N)'	System	03 May 2021 06:59:55

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-05-03T01:59:52-05:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '978c3077-75c5-4600-afe6-caa7e155db64'	System	03 May 2021 06:59:55
User entered '03 May 2021 01:59:52'	System	03 May 2021 06:59:55

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:23:15

**US3042309**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:59:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:23:15
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:23:15

US3042309

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:59:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:45:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-01T00:03:43-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '429bcdab-d7e1-4d42-a018-8b4e566fc121'	(b) (4), (b) (6)	01 Mar 2021 06:03:56
User entered 'No (N)'	System	01 Mar 2021 06:03:56

**US3042309**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:45:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A12BA993-73CA-4734-A697-3A8345EB4FDE)', Time: '2021-03-01T00:03:52-06:00', User OID: 'PatientReportedOutcome (US3042309)', ODM File OID: '429bcdab-d7e1-4d42-a018-8b4e566fc121' User entered '01 Mar 2021 00:03:52'	(b) (4), (b) (6) System	01 Mar 2021 06:03:56
	System	01 Mar 2021 06:03:56

**US3042309**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 20:39:37

**US3042309**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 20:39:37

**US3042309**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 20:39:37

**US3042309**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 20:39:37

**US3042309**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:42
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 20:39:44

**US3042309**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:42
User entered 'I'	(b) (4), (b) (6) System	25 Nov 2020 20:39:44

**US3042309**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:40:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 17:12:44
	(b) (4), (b) (6)	

**US3042309**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:40:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '21 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 17:12:44
	(b) (4), (b) (6)	

**US3042309**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:40:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Dec 2020 17:12:44
	(b) (4), (b) (6)	

**US3042309**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:40:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 17:12:44
	(b) (4), (b) (6)	

**US3042309**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:40:33
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 17:12:51
	(b) (4), (b) (6)	

**US3042309**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:40:33
User entered 'I'	(b) (4), (b) (6) System	21 Dec 2020 17:12:51

**US3042309**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:17:05
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 19:56:13

**US3042309**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:17:05
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 19:56:13

**US3042309**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:17:05
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Jan 2021 19:56:13

**US3042309**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:17:05
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 19:56:13

**US3042309**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:17:05
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 19:56:20

**US3042309**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:17:05
User entered '1'	(b) (4), (b) (6) System	19 Jan 2021 19:56:20

**US3042309**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:46
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 16:08:48

**US3042309**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:46
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '18 Feb 2021'	(b) (4), (b) (6)	18 Feb 2021 16:08:48

**US3042309**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:46
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Feb 2021 16:08:48

**US3042309**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:59:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:46
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 16:08:48

**US3042309**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:46
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 16:08:54

**US3042309**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:46
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 16:08:54
	System	

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:46:09

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '09 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:46:09

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[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 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:46:09

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User entered 'VISIT4'	(b) (4), (b) (6) System	09 Mar 2021 16:46:09

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'No (N)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:09:31

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:08:20

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 20:08:20

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:46:15

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '09 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:46:15

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:46:20

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '09 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:46:20

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered '08:45'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:46:20

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User entered '09 Mar 2021 08:45'	(b) (4), (b) (6) System	09 Mar 2021 16:46:20

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:10
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:46:22

**US3042309**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:08:20
User entered 'I'	(b) (4), (b) (6) System	09 Mar 2021 16:46:22

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:28

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:59:37**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '13:57'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:28

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:59:37**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User entered '16 Sep 2020 13:57'	(b) (4), (b) (6) System	05 Nov 2020 17:00:28

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:59:37**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:28

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:59:37**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:28

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Day 1 (Day 1)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '14 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User entered empty.	(b) (4), (b) (6) System	05 Nov 2020 17:00:59

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 14:59:37**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:59

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Day 2 (Day 2)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '15 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User entered empty.	(b) (4), (b) (6) System	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

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Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:05

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Day 3 (Day 3)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '98'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User entered '%'	(b) (4), (b) (6) System	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '37.1' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Severe (Severe)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Severe (Severe)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:01:53

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Day 4 (Day 4)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '17 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User entered empty.	(b) (4), (b) (6) System	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:02:18

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Day 5 (Day 5)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '18 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '99'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User entered '%'	(b) (4), (b) (6) System	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '97.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:01

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Day 6 (Day 6)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '19 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 14:59:37**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '99'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User entered '%'	(b) (4), (b) (6) System	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '98.0' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:59:37

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:03:48

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:49

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 14:59:37**

[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 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:49

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 14:59:37**

[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 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:49

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:49

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:37

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:49

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:37

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:49

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:37

[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 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:49

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:37

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:49

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 14:59:37**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:00:49

US3042309

Folder: Covid-19 Assessment 16 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:59:37

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User entered '0'	(b) (4), (b) (6) System	05 Nov 2020 17:00:49

**US3042309**

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:15
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:24:29

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '18 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '20 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 16:57:37

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:57:26

US3042309

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4) (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 3 and Saliva Day 5 samples with dates of 18SEP2020 and 20SEP2020 respectively; however, Saliva Log is not completed. Please reconcile or clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:35
User closed query 'Per GCL Lab Recon: GCL has a Swab sample with date of 16SEP2020; however, there is no Contact nor Diagnostic Test form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 11:40:46
Query 'Per GCL Lab Recon: GCL has Saliva Day 3 and Saliva Day 5 samples with dates of 18SEP2020 and 20SEP2020 respectively; however, Saliva Log is not completed. Please reconcile or clarify. ' answered with 'FORM UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:04:18
Query 'Per GCL Lab Recon: GCL has a Swab sample with date of 16SEP2020; however, there is no Contact nor Diagnostic Test form completed. Please reconcile or clarify.' answered with 'FORMS UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	05 Nov 2020 17:04:10
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3 and Saliva Day 5 samples with dates of 18SEP2020 and 20SEP2020 respectively; however, Saliva Log is not completed. Please reconcile or clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 09:43:54
User opened query 'Per GCL Lab Recon: GCL has a Swab sample with date of 16SEP2020; however, there is no Contact nor Diagnostic Test form completed. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 09:41:49
User entered '16 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:57:26

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:57:26

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User entered 'SICKD1'	(b) (4), (b) (6) System	16 Sep 2020 20:57:26

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '13:57'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User entered '16 Sep 2020 13:57'	(b) (4), (b) (6) System	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '190.5' cm	(b) (4) Rylea Gulick (b) (4)	16 Sep 2020 20:58:20
DataPoint set to visible.	(b) (4) System	16 Sep 2020 20:57:26

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '139.4' kg	(b) (4) Rylea Gulick (b) (4)	16 Sep 2020 20:58:20
DataPoint set to visible.	(b) (4) System	16 Sep 2020 20:57:26

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '37.1' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '63'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User entered 'bpm'	(b) (4), (b) (6) System	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '130'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '90'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 20:58:20

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:17:07

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:59:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:17:07

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:24

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:59:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:24

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 14:59:37**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:28

**US3042309**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 14:59:37**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:17:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:58:28

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 21:12:59
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 21:12:59
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	13 Jan 2021 21:12:59
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:59:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 21:12:59

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 21:13:06
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Apr 2021 18:45:37
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:40:52

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	13 Jan 2021 21:15:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	13 Jan 2021 21:13:06
	(b) (4)	

US3042309

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:59:37

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 11:38:11
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 18:45:43
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 18:45:37
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:21:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:40:52

US3042309

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:59:37

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4)	13 Jan 2021 21:15:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 21:13:06
	(b) (4)	

US3042309

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:59:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Placebo (Placebo)' reason for change:	Rylea Gulick (b) (4)	13 Jan 2021 21:15:34
Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 21:13:06
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:10:56
User entered 'Placebo (Placebo)' reason for change:	Rylea Gulick (b) (4)	13 Jan 2021 21:15:34
Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 21:13:06
	(b) (4)	

US3042309

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:59:37

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:10:56
User entered 'Placebo (Placebo)' reason for change:	Rylea Gulick (b) (4)	13 Jan 2021 21:15:34
Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 21:13:06
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	13 Jan 2021 21:15:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 21:13:06
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User entered '1'	System	13 Jan 2021 21:15:34
User entered empty.	System	13 Jan 2021 21:13:06

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:59:37**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 21:13:06

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 21:13:11
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 21:13:11
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '13:33'	Rylea Gulick (b) (4)	13 Jan 2021 21:13:11
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
User entered '13 Jan 2021 13:33'	(b) (4), (b) (6) System	13 Jan 2021 21:13:11

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:59:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 21:13:17
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 21:13:17
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '13:35'	Rylea Gulick (b) (4)	13 Jan 2021 21:13:17
	(b) (4)	

**US3042309**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:59:37**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:26:35
User entered '13 Jan 2021 13:35'	(b) (4), (b) (6)	
	System	13 Jan 2021 21:13:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 14:59:37**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:29:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	24 Sep 2020 15:13:28
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 20:27:10
	(b) (4)	

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	24 Sep 2020 15:25:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:25:53
Data point term sent to Coder	System	24 Sep 2020 15:25:15
User entered 'STREP THROAT'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '18 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 15:24:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:57:31
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 15:08:59
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 15:08:44
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 03:44:20
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	03 Dec 2020 15:08:52
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	03 Dec 2020 15:08:52
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	03 Dec 2020 15:08:44
User entered '29 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 15:08:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 15:24:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	24 Sep 2020 15:24:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 15:24:45
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:45
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 15:24:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

US3042309

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	24 Sep 2020 15:24:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 15:24:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:45
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 15:24:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	24 Sep 2020 15:24:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 15:24:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:45
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 15:24:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'None (NONE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 15:08:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User entered '0'	(b) (4), (b) (6) System	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:50
User entered '1'	(b) (4), (b) (6) System	24 Sep 2020 15:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:50

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:14:43

US3042309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: Please review if the AEs recorded here (lines 2-10) are reported symptoms of SARS-COV-2. If yes, these are to be recorded on the Symptom log in the Covid-19 Assessment folder and should be removed from the AE page (even if the subject did not test positive). Please update as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:57:12
Query 'Per CDM: Please review if the AEs recorded here (lines 2-10) are reported symptoms of SARS-COV-2. If yes, these are to be recorded on the Symptom log in the Covid-19 Assessment folder and should be removed from the AE page (even if the subject did not test positive). Please update as appropriate, else clarify. ' answered with 'THIS IS A SYMPTOM OF COVID-19, HOWEVER, THIS WAS FROM SUBJECTS DIAGNOSIS OF STREP THROAT.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:48:40
User opened query 'Per CDM: Please review if the AEs recorded here (lines 2-10) are reported symptoms of SARS-COV-2. If yes, these are to be recorded on the Symptom log in the Covid-19 Assessment folder and should be removed from the AE page (even if the subject did not test positive). Please update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 08:45:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 19:53:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 19:53:35
Data point term sent to Coder	System	11 Nov 2020 19:53:02
User entered 'MILD SORE THROAT'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	11 Nov 2020 19:52:52
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Nov 2020 19:52:17
	(b) (4)	

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '29 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Rylea Gulick (b) (4)	11 Nov 2020 19:52:17
	(b) (4)	

US3042309

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:51:25
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:50:35
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 09:31:53
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:43
	(b) (4), (b) (6)	
User entered '0'	System	11 Nov 2020 19:52:52
User entered '1'	System	11 Nov 2020 19:52:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:14:43

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:14:50

US3042309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per MM: this subject presented with mild sore throat, moderate chills, mild cough, moderate fatigue, severe muscle ache, severe bodyache, mild headache (onsets 16Sep2020) - please confirm if these are symptoms of covid and if the patient was evaluated for potential COVID-19 infection. If confirmed symptoms, these need to be recorded in the Symptom log only and removed from the AE page.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:58:02
Query 'Per MM: this subject presented with mild sore throat, moderate chills, mild cough, moderate fatigue, severe muscle ache, severe bodyache, mild headache (onsets 16Sep2020) - please confirm if these are symptoms of covid and if the patient was evaluated for potential COVID-19 infection. If confirmed symptoms, these need to be recorded in the Symptom log only and removed from the AE page.' answered with 'THIS IS A SYMPTOM OF COVID-19, HOWEVER, THIS WAS FROM SUBJECTS DIAGNOSIS OF STREP THROAT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:48:52
User opened query 'Per MM: this subject presented with mild sore throat, moderate chills, mild cough, moderate fatigue, severe muscle ache, severe bodyache, mild headache (onsets 16Sep2020) - please confirm if these are symptoms of covid and if the patient was evaluated for potential COVID-19 infection. If confirmed symptoms, these need to be recorded in the Symptom log only and removed from the AE page.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Dec 2020 08:52:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:11:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 00:11:39
Data point term sent to Coder	System	11 Nov 2020 19:54:04

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'MODERATE CHILLS'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '29 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

US3042309

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:51:44
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:50:42
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 09:32:12
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:50
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 19:53:34

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:14:50

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:11

US3042309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Nov 2020 19:55:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 19:55:35
Data point term sent to Coder	System	11 Nov 2020 19:55:06
User entered 'MILD COUGH'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

US3042309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '29 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

US3042309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

US3042309

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:51:56
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:49:00
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 09:32:36
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:11
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 19:54:26

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:11

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:19

US3042309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:12:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:12:35
Data point term sent to Coder	System	11 Nov 2020 19:56:07
User entered 'MODERATE FATIGUE'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '29 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Rylea Gulick (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

US3042309

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:52:16
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:49:11
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 09:32:53
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:19
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 19:55:17

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:19

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:02

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Nov 2020 22:33:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:33:37
Data point term sent to Coder	System	11 Nov 2020 20:00:18
User entered 'SEVERE MUSCLE ACHES'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '29 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

US3042309

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:52:28
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:49:20
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 09:33:11
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:02
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 19:59:33

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:02

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:27

US3042309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #6. Please reconcile and update so there is no overlap or delete if this is a duplicate record. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:56:58
Query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #6. Please reconcile and update so there is no overlap or delete if this is a duplicate record. Otherwise, clarify.' answered with 'THIS IS A SYMPTOM OF COVID-19, HOWEVER, THIS WAS FROM SUBJECTS DIAGNOSIS OF STREP THROAT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:49:36
User opened query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #6. Please reconcile and update so there is no overlap or delete if this is a duplicate record. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 19:37:21
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:33:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:33:37
Data point term sent to Coder	System	11 Nov 2020 20:01:18
User entered 'SEVERE BODY ACHES'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '29 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

US3042309

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:52:43
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:50:17
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 09:33:31
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:27
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 20:00:46

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:27

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:14:30

US3042309

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:03:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:03:35
Data point term sent to Coder	System	11 Nov 2020 20:02:19
User entered 'MILD HEADACHE'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '29 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

US3042309

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:52:59
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:49:45
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 09:33:52
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:14:30
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 20:01:55

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:14:30

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:41

US3042309

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGt: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:04:37
Data point term sent to Coder	System	11 Nov 2020 20:03:20
User entered 'MILD NASAL CONGESTION'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '29 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User entered empty.	(b) (4), (b) (6) System	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

US3042309

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

US3042309

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:53:13
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:49:54
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 09:34:11
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:15:41
User entered '0'	(b) (4), (b) (6) System	11 Nov 2020 20:02:32

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:15:41

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:24:30
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:05:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 20:05:36
Data point term sent to Coder	System	11 Nov 2020 20:04:21
User entered 'MILD RUNNY NOSE'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

**Start date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:24:30
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:03:40
	System	

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**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '29 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:24:30
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:03:40
	System	

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

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**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

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**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:55:29
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT APPLICABLE PER PI' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Dec 2020 14:50:04
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 09:34:38
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 15:24:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:03:40

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**Form: Adverse Events (10)**

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**Serious Adverse Event Derived (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:24:30
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:03:40
	System	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:24:30
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 20:03:40
	System	

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:24:30
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:36:59
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:21
	(b) (4), (b) (6)	
User entered	System	18 Feb 2021 18:53:09
'USA-US052-2021-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	18 Feb 2021 18:53:09
	(b) (4), (b) (6)	

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:37:00
	(b) (4), (b) (6)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGt: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Stab wound, LLT: Stab wound - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 21:02:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 21:02:13
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 21:01:33
User entered 'Abdominal Stab Wound'	Jamie Thompson (b) (4)	17 Feb 2021 21:01:12
	(b) (4)	

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**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 14:37:02
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 14:37:05
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Form: Adverse Events (11)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 14:37:09
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:37:15
User entered '13 Feb 2021'	(b) (4), (b) (6) Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 14:37:23
User entered empty.	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 21:01:12

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:37:25
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	09 Mar 2021 16:47:59
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 16:00:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 16:00:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	02 Mar 2021 16:00:06
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 21:01:12
User entered empty.	Jamie Thompson (b) (4)	17 Feb 2021 21:01:12
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:56:45
	(b) (4), (b) (6)	
Query 'Please verify date, subject was discharged from hospital on 16 Feb 2021, that should end the SAE and open an AE' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:56:42
	(b) (4), (b) (6)	
User opened query 'Please verify date, subject was discharged from hospital on 16 Feb 2021, that should end the SAE and open an AE' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:45:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 14:43:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:06
	(b) (4), (b) (6)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Mar 2021 16:48:33
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	09 Mar 2021 16:48:33
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Mar 2021 16:47:59
User entered '04 Mar 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4)	09 Mar 2021 16:47:59
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 20:55:33
	(b) (4), (b) (6)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'END DATE IS CURRENTLY NOT AVAILABLE' (Site from Safety).	Rylea Gulick (b) (4)	02 Mar 2021 16:00:19
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:10:23
	(b) (4), (b) (6)	

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**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 14:39:30
User entered empty.	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 21:37:33
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 13:55:18
User entered empty.	System	17 Feb 2021 21:01:12

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Severity

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 23:04:29
	(b) (4), (b) (6)	
User closed query 'Please have Dr. Enszt reassess, event meets grade 4 criteria' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 23:04:16
	(b) (4), (b) (6)	
Query 'Please have Dr. Enszt reassess, event meets grade 4 criteria' answered with 'PI REASSESSED' (Site from CRA).	Rylea Gulick (b) (4)	22 Apr 2021 20:13:08
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	22 Apr 2021 20:12:46
	(b) (4)	
User opened query 'Please have Dr. Enszt reassess, event meets grade 4 criteria' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:07:49
	(b) (4), (b) (6)	
Query 'Please verify severity, Grade 1/Mild seems inadequate for a hospitalization and stabbing with surgery' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:05:37
	(b) (4), (b) (6)	
User opened query 'Please verify severity, Grade 1/Mild seems inadequate for a hospitalization and stabbing with surgery' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:47:24
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide event severity.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 20:55:36
	(b) (4), (b) (6)	
Query 'PV Query: Please provide event severity.' answered with 'SEVERITY ANSWERED' (Site from Safety).	Rylea Gulick (b) (4)	02 Mar 2021 16:00:27
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 16:00:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 16:00:06
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	02 Mar 2021 16:00:06
	(b) (4)	
User opened query 'PV Query: Please provide event severity.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:06:22
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 21:01:12
User entered empty.	Jamie Thompson (b) (4)	17 Feb 2021 21:01:12
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 14:46:06
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) (6) (b) (4), (b) (6)	02 Mar 2021 20:55:40
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 'ANSWER IS CORRECT' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:00:37
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	18 Feb 2021 18:50:40
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) (b) (4), (b) (6)	18 Feb 2021 17:58:44
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	17 Feb 2021 21:01:12
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 15:09:54
User entered '0'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 15:09:56
User entered '0'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 15:09:58
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	18 Feb 2021 18:50:40
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	18 Feb 2021 18:50:40
User entered '1' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	18 Feb 2021 18:50:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	17 Feb 2021 21:01:12
User entered '0'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 15:10:01
User entered '13 Feb 2021'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:10:03
	(b) (4), (b) (6)	
User entered '16 Feb 2021'	Jamie Thompson (b) (4)	17 Feb 2021 21:01:12
	(b) (4)	

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:04:45
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 14:59:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:04:56
User entered empty.	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:05:08
User entered '0'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:05:21
User entered '0'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:05:32
User entered '0'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:05:44
User entered 'Not Related (NOT RELATED)'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:06:08
User entered 'Not Related (NOT RELATED)'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 23:05:56
	(b) (4), (b) (6)	
User closed query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 20:55:45
	(b) (4), (b) (6)	
Query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'ENTRY UPDATED' (Site from Safety).	Rylea Gulick (b) (4)	02 Mar 2021 16:00:43
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	02 Mar 2021 16:00:06
	(b) (4)	
User opened query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:06:39
	(b) (4), (b) (6)	
User entered 'None (NONE)'	Jamie Thompson (b) (4)	17 Feb 2021 21:01:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 14:59:21
User entered '0'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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Folder: Adverse Events

Form: Adverse Events (11)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'This should be checked YES, there is meds listed on the conmed page for event.' (Site from CRA).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 15:09:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 15:08:33
Query 'This should be checked YES, there is meds listed on the conmed page for event.' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	27 Apr 2021 13:48:03
User entered '1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	27 Apr 2021 13:47:58
User opened query 'This should be checked YES, there is meds listed on the conmed page for event.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:09:39
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:08:51
User closed query 'Please verify, there is a number of meds listed on the discharge summary, please update conmed page as required.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:06:33
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 23:06:21
Query 'Please verify, there is a number of meds listed on the discharge summary, please update conmed page as required.' answered with 'CON MED LOG WAS UPDATED, HOWEVER, NO MEDICATIONS GIVEN FOR ACTUAL AE' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	22 Apr 2021 20:13:47
User opened query 'Please verify, there is a number of meds listed on the discharge summary, please update conmed page as required.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 14:58:59

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	31 Mar 2021 14:22:54
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly.' answered with 'MEDICATIONS WILL BE REVIEWED AND ADDED IF NECESSARY' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 20:03:56
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	17 Mar 2021 01:45:33
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:26:43

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Mar 2021 21:26:38
User closed query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 13:44:49
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'SURGICAL TREATMENTS ARE RECORDING IN CON PROCEDURES LOG' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:15:04
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 13:54:32
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 13:53:31

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Form: Adverse Events (11)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 12:12:50
User closed query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 20:55:53
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 20:55:50
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'ENTRY UPDATED' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:02:31

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly.' answered with 'MED WILL BE UPDATED' (Site from Safety). User entered '1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:00:52
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 16:00:06 26 Feb 2021 15:07:53
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 15:07:29

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 15:07:11
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 15:06:57
User entered '0'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 23:09:53
User closed query 'Per CDM CLR re-query: Response noted; however no entry has been updated. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 01:23:54
Query 'Per CDM CLR re-query: Response noted; however no entry has been updated. Kindly review and update accordingly. Thank you.' answered with 'FORM WILL BE UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:48:54
User opened query 'Per CDM CLR re-query: Response noted; however no entry has been updated. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 12:31:30
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 12:30:34
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:02:38
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Feb 2021 02:17:21

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:59:36
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 13:44:53
	(b) (4), (b) (6)	
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'OUTCOME IS UPDATED' (Site from Safety).	Rylea Gulick (b) (4)	10 Mar 2021 19:14:44
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 13:55:57
	(b) (4), (b) (6)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	09 Mar 2021 16:48:33
	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 20:55:59
	(b) (4), (b) (6)	
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'OUTCOME WILL BE UPDATED WHEN AVAILABLE' (Site from Safety).	Rylea Gulick (b) (4)	02 Mar 2021 16:02:48
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:08:47
	(b) (4), (b) (6)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jamie Thompson (b) (4)	17 Feb 2021 21:01:12
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 14:59:38
User entered empty.	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:59:44
	(b) (4), (b) (6)	
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly. If not to be included, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 15:15:01
	(b) (4), (b) (6)	
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly. If not to be included, please state so in your response.' answered with 'con med page will be updated' (Site from Safety).	Rylea Gulick (b) (4)	09 Apr 2021 13:23:42
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Additionally, the discharge summary included discharge medications: Afrin, Amitriptyline, Clonidine, Lexapro, Lisinopril, Melatonin, Multivitamin, Nicotine gum, Testosterone cypionate, and Zaleplon. Please confirm if these should be included in the concomitant medications and if so, please update the eCRF accordingly. If not to be included, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 16:48:41
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed prior to or during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 13:44:57
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 13:44:55
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'PAPERS HAVE ALREADY BEEN EMAILED.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:14:32
Query 'PV Query: Please provide the results of any COVID-19 testing performed prior to or during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'NO TEST INFORMATION AVAILABLE.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:14:21

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:37

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed prior to or during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 13:54:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 13:54:04
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed prior to or during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 20:56:06
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 20:56:03
Query 'PV Query: Please provide the results of any COVID-19 testing performed prior to or during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'RESULTS ARE NOT AVAILABLE.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:10:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'RESULTS WERE SENT TO SAFETY_MODERNA@IQVIA.COM ON 18FEB2021' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:07:37

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:37

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Mar 2021 16:03:23
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Mar 2021 16:03:23
User entered 'SUBJECT SUFFERED AN ABDOMINAL STAB WOUND.' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:03:23
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed prior to or during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 15:08:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 15:07:37
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Feb 2021 21:01:12
User entered empty.	Jamie Thompson (b) (4) (b) (4)	17 Feb 2021 21:01:12

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 21:01:12

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 21:01:12

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 21:01:12

US3042309

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:59:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Apr 2021 13:25:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:25:37
Data point term sent to Coder	System	09 Apr 2021 13:24:43
User entered 'HYPERTENSION'	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '01 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 13:24:35

**US3042309**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 13:24:35

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:59:37

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:13:14
Query 'There are numerous meds listed in the subject discharge summary for the SAE, please update conmed page accordingly.' canceled (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 15:13:11
User opened query 'There are numerous meds listed in the subject discharge summary for the SAE, please update conmed page accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 15:01:47
User closed query 'Per ETRTR: According to SAE "Abdominal Stab Wound", medications were dosed, but no medications are present in this folder. Please add as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Apr 2021 15:01:47
Query 'Per ETRTR: According to SAE "Abdominal Stab Wound", medications were dosed, but no medications are present in this folder. Please add as applicable, thanks.' answered with 'THESE WILL BE REVIEWED AND UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:16:16
User opened query 'Per ETRTR: According to SAE "Abdominal Stab Wound", medications were dosed, but no medications are present in this folder. Please add as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 22:36:19
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:14

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 20:28:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 20:28:40
Data point term sent to Coder	System	24 Aug 2020 20:28:16
User entered 'TYLENOL'	Rylea Gulick (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'MIGRAINES'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '500'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

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[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'UN UNK 2008'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 20:27:58

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 20:27:58

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
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.	Coder Import (b) (4) (b) (4)	24 Aug 2020 20:29:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 20:29:36
Data point term sent to Coder	System	24 Aug 2020 20:29:17
User entered 'IBUPROFEN'	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'MIGRAINES'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '600'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'UN UNK 2008'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 20:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 20:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Aug 2020 20:30:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 20:30:36
Data point term sent to Coder	System	24 Aug 2020 20:30:18
User entered 'SUMATRIPTAN'	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'MIGRAINES'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'UN UNK 2008'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 20:29:41

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 20:29:41

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 22:30:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 22:30:37
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4)	01 Sep 2020 22:29:28 01 Sep 2020 22:29:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:09:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:09:49
Data point term sent to Coder User entered 'TOPIRAMATE'	System Rylea Gulick (b) (4)	24 Aug 2020 20:30:19 24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	01 Sep 2020 22:29:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 22:29:17
User entered 'MIGRAINES' reason for change: Data Entry Error	Rylea Gulickt (b) (4) (b) (4)	01 Sep 2020 22:29:17
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 20:30:04
User entered empty.	Rylea Gulickt (b) (4) (b) (4)	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '150'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	01 Sep 2020 22:29:42
User entered 'UN UNK 2008' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	01 Sep 2020 22:29:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Aug 2020 20:30:04
User entered 'UN UNK ' (non-conformant).	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	24 Aug 2020 20:30:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 20:30:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:08
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 20:30:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 20:30:04

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 20:30:04

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 22:31:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 22:31:37
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4)	01 Sep 2020 22:30:29 01 Sep 2020 22:30:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 20:32:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 20:32:40
Data point term sent to Coder User entered 'ESCITALOPRAM'	System Rylea Gulick (b) (4)	24 Aug 2020 20:31:20 24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	01 Sep 2020 22:30:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 22:30:02
User entered 'DEPRESSION' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	01 Sep 2020 22:30:02
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 20:30:29
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '20'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	01 Sep 2020 22:30:15
User entered 'UN UNK 2008' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	01 Sep 2020 22:30:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Aug 2020 20:30:29
User entered 'UN UNK ' (non-conformant).	Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 20:30:29

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 20:30:29

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:14:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:14:14
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	30 Oct 2020 19:26:12 30 Oct 2020 19:26:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 21:22:14
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 Oct 2020 21:22:14
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 15:14:38 14 Oct 2020 15:14:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:11:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:11:53
Data point term sent to Coder	System	16 Sep 2020 21:00:04

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'IBUPROFEN'	Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM, per DM CLR re-query: Thank you for adding STREP THROAT to the AE eCRF (AE #1). Please review if the other indications listed here should also be recorded on the AE eCRF so there are corresponding AE records to match indications. Please also note that the start date for this medication (15 Sep 2020) is prior to the start date of the start date of AE #1 (18 Sep 2020). Please review, reconcile and update as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Nov 2020 07:00:32
Query 'Per CDM, per DM CLR re-query: Thank you for adding STREP THROAT to the AE eCRF (AE #1). Please review if the other indications listed here should also be recorded on the AE eCRF so there are corresponding AE records to match indications. Please also note that the start date for this medication (15 Sep 2020) is prior to the start date of the start date of AE #1 (18 Sep 2020). Please review, reconcile and update as appropriate, else clarify.' answered with 'AE LOG HAS BEEN UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Nov 2020 20:04:32
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding AE records that match these conditions. Please note, this medication was started after the period of recording solicited events so there should be corresponding AE records to match indications. Please update to record the corresponding AEs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 09:07:40
User opened query 'Per CDM, per DM CLR re-query: Thank you for adding STREP THROAT to the AE eCRF (AE #1). Please review if the other indications listed here should also be recorded on the AE eCRF so there are corresponding AE records to match indications. Please also note that the start date for this medication (15 Sep 2020) is prior to the start date of the start date of AE #1 (18 Sep 2020). Please review, reconcile and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 09:07:34

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User closed query ' Per DM CLR: Please review Indication and please update to specify the location of Muscle and BODY Aches. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:27:15
Query 'Per DM CLR: Please review Indication and please update to specify the location of Muscle and BODY Aches. Please update as appropriate or provide clarification.	(b) (4), (b) (6)	
' answered with 'ENTRY UPDATED' (Site from DM).		
User entered 'FATIGUE, GENERALIZED MUSCLE AND BODY ACHES, HEADACHE DUE TO STREP THROAT' reason for change: Data Entry Error	Rylea Gulick (b) (4)	30 Oct 2020 19:26:11
	(b) (4)	
User opened query 'Per DM CLR: Please review Indication and please update to specify the location of Muscle and BODY Aches. Please update as appropriate or provide clarification.	Rylea Gulick (b) (4)	30 Oct 2020 19:26:01
' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding AE records that match these conditions. Please note, this medication was started after the period of recording solicited events so there should be corresponding AE records to match indications. Please update to record the corresponding AEs as appropriate. Otherwise, clarify.'	Rylea Gulick (b) (4)	14 Oct 2020 15:14:15
' answered with 'ENTRY UDPATED' (Site from DM).	(b) (4)	
User entered 'FATIGUE, MUSCLE AND BODY ACHES, HEADACHE DUE TO STREP THROAT' reason for change: Data Entry Error	Rylea Gulick (b) (4)	14 Oct 2020 15:14:08
	(b) (4)	
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding AE records that match these conditions. Please note, this medication was started after the period of recording solicited events so there should be corresponding AE records to match indications. Please update to record the corresponding AEs as appropriate. Otherwise, clarify.'	(b) (4), (b) (6)	14 Oct 2020 10:19:05
(Site from DM).	(b) (4), (b) (6)	

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User entered 'SOLICITED SYMPTOMS-FATIGUE, Rylea Gulick (b) (4) MUSCLE AND BODY ACHES, HEADACHE'	(b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '800'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the the start dates of the indicated AEs. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 07:56:18
Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the the start dates of the indicated AEs. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'START DATE IS CORRECT; SUBJECT STARTED TAKING MEDICATION PRIOR TO DIAGNOSIS.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:49:51
User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the the start dates of the indicated AEs. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 19:36:53
User entered '15 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:37

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query ' Per DM CLR: Was this medication taken for solicited event? = YES. However, the start date of this medication was outside the period of recording solicited events. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 08:55:53
Query ' Per DM CLR: Was this medication taken for solicited event? = YES. However, the start date of this medication was outside the period of recording solicited events. Please review and update accordingly. Otherwise, clarify.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 15:14:22
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 15:14:19
User opened query ' Per DM CLR: Was this medication taken for solicited event? = YES. However, the start date of this medication was outside the period of recording solicited events. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 10:19:22
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:59:38

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:59:38

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Sep 2020 15:26:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:26:51
Data point term sent to Coder User entered 'AMOXICILLIN'	System Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:26:20 24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'STREP THROAT'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '500'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'twice daily (BID)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '19 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or provide clarification for continued use of the medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Feb 2021 13:14:32
Query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or provide clarification for continued use of the medication. ' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 16:59:11
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 16:59:01
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Jan 2021 14:58:41
User opened query 'Per CDM, DM CLR re-query: Response noted. Please review if a stop date should be recorded or provide clarification for continued use of the medication. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Jan 2021 14:58:39
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'CON MED WILL BE REVIEWED AND UPDATED AS NECESSARY' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 16:16:41
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Jan 2021 04:38:35
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered '29 Sep 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	25 Jan 2021 16:59:01
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 15:25:40
	(b) (4)	

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User entered '2'	(b) (4), (b) (6) System	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User entered '1'	(b) (4), (b) (6) System	24 Sep 2020 15:25:40

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:53:04
User entered '804 (804)'	(b) (4), (b) (6) System	24 Sep 2020 15:25:40

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN OPIOID DEPENDENCE, PRODUCT: BUPRENORPHINE HYDROCHLORIDE;NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: SUBOXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 23:57:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 23:57:49
Data point term sent to Coder	System	02 Mar 2021 16:15:03
Data point term sent to Coder	System	02 Mar 2021 16:12:59
User entered 'SUBOXONE'	Rylea Gulick (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'NARCOTIC ABUSE' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	02 Mar 2021 16:14:12
User entered 'NARCAN ABUSE'	(b) (4) Rylea Gulick (b) (4)	02 Mar 2021 16:12:45

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 01:47:03
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:15:57
User entered '16/4' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:15:47
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:17:51
User entered '16'	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Other (OTHER)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'SUBLINGUAL'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '18 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 16:12:45

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 16:12:45

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 06:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 06:48:54
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4)	09 Apr 2021 13:26:47 09 Apr 2021 13:26:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 04:47:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 04:47:37
Data point term sent to Coder User entered 'AMITHRIPTYLINE'	System Rylea Gulick (b) (4)	07 Apr 2021 20:21:30 07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'INSOMNIA' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:26:38
User entered 'ABDOMINAL STABBING'	(b) (4) Rylea Gulick (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '100'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4) System	09 Apr 2021 13:26:42
User entered '01 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:26:42
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 13:26:38
User entered '01 Jun 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:26:38
User entered '16 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 20:21:10

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 20:21:10

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:28:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:28:36
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:27:48 09 Apr 2021 13:26:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:37:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:37:38
Data point term sent to Coder User entered 'CLONIDINE'	System Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:22:32 07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'HYPERTENSION' reason for change:	(b) (4)	
Data Entry Error	Rylea Gulick (b) (4)	09 Apr 2021 13:26:56
User entered 'ABDOMINAL STABBING'	(b) (4)	
	Rylea Gulick (b) (4)	07 Apr 2021 20:21:36
	(b) (4)	

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '.4'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'UN Oct 2020' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:26:56
User entered '16 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 20:21:36

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 20:21:36

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:29:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:29:43
Data point term sent to Coder User entered 'LISINOPRIL'	System Rylea Gulick (b) (4)	09 Apr 2021 13:28:49 09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	(b) (4) Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'HYPERTENSION'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '10'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	(b) (4) Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	(b) (4) Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	(b) (4) Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	(b) (4) Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	(b) (4) Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'UN Oct 2020'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	(b) (4) Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	Rylea Gulick (b) (4) (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	(b) (4) Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	(b) (4) Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Rylea Gulick (b) (4)	07 Apr 2021 20:29:42
	(b) (4)	

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 13:27:59
DataPoint activated with code reason code Data required.	Rylea Gulick (b) (4)	09 Apr 2021 13:27:19
DataPoint inactivated with code reason code Data not required.	Rylea Gulick (b) (4)	07 Apr 2021 20:29:42

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:29:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:29:43
Data point term sent to Coder	System	09 Apr 2021 13:28:49
User entered 'MELATONIN'	Rylea Gulick (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'INSOMNIA'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '10'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'UN Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:28:26

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:28:26

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 13:30:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 13:30:47
Data point term sent to Coder	System	09 Apr 2021 13:29:51
User entered 'TESTOSTERONE'	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'LOW TESTOSTERONE'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '200'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'other (OTHER)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Q2WEEKS'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'UN UNK 2016'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:29:13

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:29:13

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 07:57:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 07:57:45
Data point term sent to Coder	System	09 Apr 2021 13:29:51
User entered 'TOPIRAMATS'	Rylea Gulick (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'ABDOMINAL STABBING'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '150'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '16 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 13:29:44

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 13:29:44

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZALEPLON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:33:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 13:33:41
Data point term sent to Coder	System	09 Apr 2021 13:32:54
User entered 'ZALEPLON'	Rylea Gulick (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'INSOMNIA'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '10'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '16 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:32:20

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:32:20

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 14:48:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 14:48:45
Data point term sent to Coder	System	09 Apr 2021 13:45:12
User entered 'NICOTINE GUM'	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'SMOKING PROPHYLAXIS'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '4'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

US3042309

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'UN Jan 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:44:34

**US3042309**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:59:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 13:44:34

US3042309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:59:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:27:11
	(b) (4), (b) (6)	
User closed query 'Per ETRTR: Please add Concomitant procedure performed for SAE "Abdominal Stab Wound", thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:26:58
	(b) (4), (b) (6)	
Query 'Per ETRTR: Please add Concomitant procedure performed for SAE "Abdominal Stab Wound", thanks.' answered with 'updated' (Site from CRA).	Jamie Thompson (b) (4)	08 Mar 2021 21:43:00
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Thompson (b) (4)	08 Mar 2021 21:42:50
	(b) (4)	
User opened query 'Per ETRTR: Please add Concomitant procedure performed for SAE "Abdominal Stab Wound", thanks.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 22:37:33
	(b) (4), (b) (6)	
User entered 'No (N)'	Rylea Gulick (b) (4)	24 Aug 2020 20:31:17
	(b) (4)	

US3042309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered '13 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:54:26

US3042309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'EXPLORATROY LAPAROTOMY'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:54:26

**US3042309**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Adverse Event (AE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:54:26

**US3042309**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 14:59:37**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:54:26

**US3042309**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 14:59:37**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:43
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '13 Feb 2021'	(b) (4) Rylea Gulick (b) (4)	09 Mar 2021 16:54:46
	(b) (4)	

**US3042309**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:43
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered 'ABDOMINAL WALL RECONSTRUCTION'	Rylea Gulick (b) (4)	09 Mar 2021 16:54:46
	(b) (4)	

**US3042309**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:43
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Adverse Event (AE)'	(b) (4) Rylea Gulick (b) (4)	09 Mar 2021 16:54:46
	(b) (4)	

US3042309

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:59:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:43
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	09 Mar 2021 16:54:46
	(b) (4)	

**US3042309**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 14:59:37**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:46
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered '13 Feb 2021'	(b) (4) Rylea Gulick (b) (4)	09 Mar 2021 16:54:53
	(b) (4)	

**US3042309**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'TAP BLOCK'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 16:54:53

**US3042309**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:46
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 22:00:08
User entered 'Adverse Event (AE)'	(b) (4) Rylea Gulick (b) (4)	09 Mar 2021 16:54:53
	(b) (4)	

**US3042309**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 14:59:37**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:10:46
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 22:00:08
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	09 Mar 2021 16:54:53
	(b) (4)	

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'USA-US052-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'David'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'Meagan'	System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'Enszt'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Miller'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '330 dakota dunes suite400'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'North sioux'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'IA'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '57049'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:16
User entered 'US'	(b) (4), (b) (6) System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 18:19:21
User entered '7'	System	23 Apr 2021 15:25:48
User entered '6'	System	12 Apr 2021 15:15:38
User entered '5'	System	16 Mar 2021 13:42:20
User entered '4'	System	10 Mar 2021 19:09:12
User entered '3'	System	02 Mar 2021 20:58:52
User entered '2'	System	19 Feb 2021 14:13:28
User entered '1'	System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'USA-US052-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'David'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'Meagan'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'Enszt'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Miller'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '330 dakota dunes suite400'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'North sioux'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'IA'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '57049'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:16
User entered 'US'	(b) (4), (b) (6) System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 18:19:21
User entered '7'	System	23 Apr 2021 15:25:48
User entered '6'	System	12 Apr 2021 15:15:38
User entered '5'	System	16 Mar 2021 13:42:20
User entered '4'	System	10 Mar 2021 19:09:12
User entered '3'	System	02 Mar 2021 20:58:52
User entered '2'	System	19 Feb 2021 14:13:28
User entered '1'	System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '18/Feb/2021 13:53'	(b) (4) System	18 Feb 2021 18:53:59

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:37

**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.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 18:54:16
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 18:53:59
	(b) (4), (b) (6)	

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'USA-US052-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'David'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Meagan'	System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'Enszt'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Miller'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered '330 dakota dunes suite400'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'North sioux'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'IA'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '57049'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:16
User entered 'US'	(b) (4), (b) (6) System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 18:19:21
User entered '7'	System	23 Apr 2021 15:25:48
User entered '6'	System	12 Apr 2021 15:15:38
User entered '5'	System	16 Mar 2021 13:42:20
User entered '4'	System	10 Mar 2021 19:09:12
User entered '3'	System	02 Mar 2021 20:58:52
User entered '2'	System	19 Feb 2021 14:13:28
User entered '1'	System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '19/Feb/2021 08:13'	(b) (4) System	19 Feb 2021 14:13:28

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:59:37

**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.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:13:35
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 14:13:28

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'USA-US052-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'David'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Meagan'	System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'Enszt'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Miller'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '330 dakota dunes suite400'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'North sioux'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'IA'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '57049'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:16
User entered 'US'	(b) (4), (b) (6) System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 18:19:21
User entered '7'	System	23 Apr 2021 15:25:48
User entered '6'	System	12 Apr 2021 15:15:38
User entered '5'	System	16 Mar 2021 13:42:20
User entered '4'	System	10 Mar 2021 19:09:12
User entered '3'	System	02 Mar 2021 20:58:52
User entered '2'	System	19 Feb 2021 14:13:28
User entered '1'	System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '02/Mar/2021 14:58'	(b) (4) System	02 Mar 2021 20:58:52

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:59:37

**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.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:08:57
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 20:58:52

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'USA-US052-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'David'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Meagan'	System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'Enszt'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'Miller'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '330 dakota dunes suite400'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'North sioux'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'IA'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered '57049'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:16
User entered 'US'	(b) (4), (b) (6) System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 18:19:21
User entered '7'	System	23 Apr 2021 15:25:48
User entered '6'	System	12 Apr 2021 15:15:38
User entered '5'	System	16 Mar 2021 13:42:20
User entered '4'	System	10 Mar 2021 19:09:12
User entered '3'	System	02 Mar 2021 20:58:52
User entered '2'	System	19 Feb 2021 14:13:28
User entered '1'	System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '10/Mar/2021 14:09'	(b) (4) System	10 Mar 2021 19:09:12

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:59:37

**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.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:15:17
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 19:09:12
	(b) (4), (b) (6)	

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'USA-US052-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'David'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'Meagan'	System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'Enszt'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Miller'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '330 dakota dunes suite400'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'North sioux'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'IA'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered '57049'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:16
User entered 'US'	(b) (4), (b) (6) System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 18:19:21
User entered '7'	System	23 Apr 2021 15:25:48
User entered '6'	System	12 Apr 2021 15:15:38
User entered '5'	System	16 Mar 2021 13:42:20
User entered '4'	System	10 Mar 2021 19:09:12
User entered '3'	System	02 Mar 2021 20:58:52
User entered '2'	System	19 Feb 2021 14:13:28
User entered '1'	System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '16/Mar/2021 06:42'	(b) (4) System	16 Mar 2021 13:42:20

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:59:37

**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.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 15:15:17
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 13:42:20
	(b) (4), (b) (6)	

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'USA-US052-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'David'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'Meagan'	System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'Ensz'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Miller'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '330 dakota dunes suite400'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'North sioux'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'IA'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '57049'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:16
User entered 'US'	(b) (4), (b) (6) System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 18:19:21
User entered '7'	System	23 Apr 2021 15:25:48
User entered '6'	System	12 Apr 2021 15:15:38
User entered '5'	System	16 Mar 2021 13:42:20
User entered '4'	System	10 Mar 2021 19:09:12
User entered '3'	System	02 Mar 2021 20:58:52
User entered '2'	System	19 Feb 2021 14:13:28
User entered '1'	System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '12/Apr/2021 10:15'	(b) (4) System	12 Apr 2021 15:15:38

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:59:37

**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.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 15:15:38

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'USA-US052-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'David'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'Meagan'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'Enszt'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Miller'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '330 dakota dunes suite400'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'North sioux'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered 'IA'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered '57049'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:16
User entered 'US'	(b) (4), (b) (6) System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 18:19:21
User entered '7'	System	23 Apr 2021 15:25:48
User entered '6'	System	12 Apr 2021 15:15:38
User entered '5'	System	16 Mar 2021 13:42:20
User entered '4'	System	10 Mar 2021 19:09:12
User entered '3'	System	02 Mar 2021 20:58:52
User entered '2'	System	19 Feb 2021 14:13:28
User entered '1'	System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '23/Apr/2021 08:25'	(b) (4) System	23 Apr 2021 15:25:48

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:59:37

**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.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:25:48

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'USA-US052-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'No (N)'	(b) (4), (b) (6) System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'David'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Meagan'	System	18 Feb 2021 18:53:09

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered 'Enszt'	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'Miller'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered '330 dakota dunes suite400'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'North sioux'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	10 Mar 2021 19:08:57
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 18:53:46
User entered 'IA'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:57
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	02 Mar 2021 20:58:52
User entered empty.	System	02 Mar 2021 20:58:52
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 18:53:46
	(b) (4), (b) (6)	
User entered '57049'	System	18 Feb 2021 18:53:09

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:16
User entered 'US'	(b) (4), (b) (6) System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:59:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	27 Apr 2021 18:19:21
User entered '7'	System	23 Apr 2021 15:25:48
User entered '6'	System	12 Apr 2021 15:15:38
User entered '5'	System	16 Mar 2021 13:42:20
User entered '4'	System	10 Mar 2021 19:09:12
User entered '3'	System	02 Mar 2021 20:58:52
User entered '2'	System	19 Feb 2021 14:13:28
User entered '1'	System	18 Feb 2021 18:53:59

**US3042309**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 14:59:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered '27/Apr/2021 11:19'	(b) (4) System	27 Apr 2021 18:19:21

US3042309

Folder: SAE USA-US052-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:59:37

**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.	David Enszt (b) (4)	28 Apr 2021 22:00:08
User entered 'I'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 18:19:21