

US3042262 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:55:45

All time stamps listed in this document are displayed in GMT

US3042262

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

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[Participant ID](#)

US3042262

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

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US3042262

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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 21:36:30

Generated On: 09 Jun 2021 14:55:45

Date of Birth (MMM yyyy)	(b) (6) 1997
Age	22
Age Units	YEARS
Age (Derived)	22
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 21:36:30

Generated On: 09 Jun 2021 14:55:45

Date of Informed Consent ( <i>dd MMM yyyy</i> )	20 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 21:36:30

Generated On: 09 Jun 2021 14:55:45

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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 21:36:31

Generated On: 09 Jun 2021 14:55:45

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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 21:36:30

Generated On: 09 Jun 2021 14:55:45

Condition	DEPRESSION
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 (2)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Condition	ANXIETY
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 21:36:30

Generated On: 09 Jun 2021 14:55:45

Condition	ATTENTION DEFICIT HYPERACTIVE DISORDER
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Condition	ASHTMA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Condition	BELLS PALSY
Start date (dd MMM yyyy)	UN JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3042262

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	20 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:09 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:09
Height ( <i>xxx.x</i> )	185.4 cm
Weight ( <i>xxx.x</i> )	140.5 kg
BMI ( <i>xxx.x</i> )	40.87492 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 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

<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 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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 21:36:31

Generated On: 09 Jun 2021 14:55:45

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 144563

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 21:36:31

Generated On: 09 Jun 2021 14:55:45

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 21:36:31

Generated On: 09 Jun 2021 14:55:45

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)	20 AUG 2020
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:09
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 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 21:36:31

Generated On: 09 Jun 2021 14:55:45

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)	20 AUG 2020
Time of assessment (00:00-23:59)	15:48 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:48
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

20 AUG 2020

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

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US3042262

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 15:16 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 15:16

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 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	14:58 (24 HR)
Collection date and time (derived)	20 AUG 2020 14:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:44	20 AUG 2020 14:44
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 15:48

PC Open Date & Time

20 AUG 2020 15:36

PC Close Date & Time

20 AUG 2020 18:06

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**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 97.9 °F

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

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

PC Time Stamp	20 AUG 2020 20:55
PC Open Date & Time	20 AUG 2020 19:01
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

21 AUG 2020 21:18

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

23 AUG 2020 00:00

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 19:34

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

24 AUG 2020 18:36

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**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

26 AUG 2020 07:31

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**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

97.6 °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 AUG 2020 06:33

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 15:49

PC Open Date & Time

20 AUG 2020 15:36

PC Close Date & Time

20 AUG 2020 18:06

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**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

20 AUG 2020 20:57

PC Open Date & Time

20 AUG 2020 19:01

PC Close Date & Time

21 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**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

21 AUG 2020 21:18

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59



US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 00:01

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**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

23 AUG 2020 19:34

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**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

24 AUG 2020 18:36

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**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

26 AUG 2020 07:32

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**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

27 AUG 2020 06:33

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**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 ☐

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 15:49
PC Open Date & Time	20 AUG 2020 15:36
PC Close Date & Time	20 AUG 2020 18:06

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**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 ☐



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 20:57
PC Open Date & Time	20 AUG 2020 19:01
PC Close Date & Time	21 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**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

49 of 2617

EAB) (1725)

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 21:19
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**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

51 of 2617

EAB) (1725)

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 00:01
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**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

53 of 2617

EAB) (1725)

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:35
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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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US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 18:36
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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

57 of 2617

EAB) (1725)

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 07:32
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**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 ☒

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 06:33
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3042262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3042262

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3042262

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3042262

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

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)	17 SEP 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 15:15
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

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)	17 SEP 2020
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 16:45
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3042262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 16:08 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 16:08

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



US3042262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

15:24 (24 HR)

Collection date and time (derived)

17 SEP 2020 15:24

US3042262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:29	17 SEP 2020 15:29
Nasopharyngeal Swab 2	No		

US3042262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**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

98.7 °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

17 SEP 2020 16:45

PC Open Date & Time

17 SEP 2020 16:28

PC Close Date & Time

17 SEP 2020 18:58

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**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 97.6 °F

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

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

PC Time Stamp	17 SEP 2020 19:53
PC Open Date & Time	17 SEP 2020 19:53
PC Close Date & Time	18 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please record your <b>TEMPERATURE</b> in °F	98.4 °F
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Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
---	------

To <b>PREVENT</b> pain or fever from occurring	False
--	-------

PC Time Stamp	18 SEP 2020 12:01
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PC Open Date & Time	18 SEP 2020 12:00
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PC Close Date & Time	19 SEP 2020 11:59
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US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**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

93.7 °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

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**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

99.1 °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

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 12:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 12:01

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**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

17 SEP 2020 16:46

PC Open Date & Time

17 SEP 2020 16:28

PC Close Date & Time

17 SEP 2020 18:58

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**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

17 SEP 2020 19:54

PC Open Date & Time

17 SEP 2020 19:53

PC Close Date & Time

18 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**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

18 SEP 2020 12:04

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**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

19 SEP 2020 12:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**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

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**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

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**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

22 SEP 2020 12:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**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

23 SEP 2020 12:01

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**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 ☐

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 16:46
PC Open Date & Time	17 SEP 2020 16:28
PC Close Date & Time	17 SEP 2020 18:58

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**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 ☐

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 19:55
PC Open Date & Time	17 SEP 2020 19:53
PC Close Date & Time	18 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:04
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**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 ☒

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**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 ☒

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EAB) (1725)

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US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**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 ☒

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EAB) (1725)

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US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:01
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**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 ☒

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:01
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3042262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042262

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

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*

US3042262

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

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 \_\_\_\_\_



US3042262

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

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

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	16:10 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 16:10
Temperature ( <i>xxx.x</i> )	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	89 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3042262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 OCT 2020
Collection time (00:00-23:59)	16:12 (24 HR)
Collection date and time (derived)	16 OCT 2020 16:12

US3042262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 10:47:33

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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

27 OCT 2020 08:05:07

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59



US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 06:55:19

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2020 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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 17:44:52
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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

12 DEC 2020 08:07:57

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 06:33:08

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 07:08:00

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 09:00:14

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 18:30:42

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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

16 JAN 2021 00:20:21

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 18:31:09

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 06:45:51

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 18:34:06

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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13 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 13:54:26

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 06:46:03

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	06 MAR 2021 06:47:02
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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

13 MAR 2021 06:46:26

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

<b>TIMEPOINT</b>	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 MAR 2021 00:01:29
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 18:30:34

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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

07 APR 2021 19:48:02

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 18:30:36

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 06:31:08

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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

27 APR 2021 14:07:20

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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

01 MAY 2021 06:26:20

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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21 JUL 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	21 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2021 23:59
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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59
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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59
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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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12 JAN 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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26 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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16 MAR 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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 <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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUL 2022 23:59



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2022 23:59

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUL 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUL 2022 23:59
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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59



US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

US3042262

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**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 ☐  
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 ☐

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59



US3042262

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:55:45

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 14:52:41

US3042262

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3042262

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042262

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042262

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3042262

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

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) \_\_\_\_\_

US3042262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

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.*

US3042262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00-23:59)	15:29 (24 HR)
Collection date and time (derived)	04 MAR 2021 15:29

US3042262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:31

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3042262

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3042262**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

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*

**US3042262**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Date of Contact	07 OCT 2020
Time of Contact	08:23
Date and Time of Contact (derived)	07 OCT 2020 08:23
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 type="checkbox"/>
Day 7	<input checked="" 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"/>

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	37.5 C	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input 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 type="checkbox"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	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 Smell	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 07 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" 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 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input 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 type="checkbox"/>
	Mild	<input checked="" 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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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	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 Smell	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 (2)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" 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 07 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	09 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

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 type="radio"/>
	Mild	<input checked="" 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 (3)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	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 Smell	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 (3)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 07 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" 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 (4)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	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 Smell	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 (4)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 (5)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 checked="" type="radio"/>
	Mild	<input 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 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 checked="" type="radio"/>
	Mild	<input 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 21:36:29

Generated On: 09 Jun 2021 14:55:45

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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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	02 OCT 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 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 07 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input 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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EAB) (1725)

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input 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 type="radio"/>
	Mild	<input checked="" 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 07 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 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 07 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 07 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	04 OCT 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 07 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 07 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	05 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

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 checked="" type="radio"/>
	Mild <input 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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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 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 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 checked="" type="radio"/>
	Mild	<input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input 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 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 07 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

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"/>

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Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Date of Visit 07 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐  
No ☒

Date of Test 07 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒  
Nasal Swab ☐  
Saliva Test ☐  
Other ☐

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

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐  
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	08:23 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 08:23
Height (xxx.x)	185.4 cm
Weight (xxx.x)	140.5 kg
Temperature (xxx.x)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	123 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

07 OCT 2020

---

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

---

US3042262

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 21:36:30

Generated On: 09 Jun 2021 14:55:45

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 OCT 2020

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

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

Visit date (dd MMM yyyy)	16 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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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Date of updated informed consent (*dd MMM yyyy*) 16 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 16 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 JAN 2021

Collection time (00:00-23:59)

08:53 (24 HR)

Collection date and time (derived)

16 JAN 2021 08:53

US3042262

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00 - 23:59)	08:55
Collection Date and Time (derived)	16 JAN 2021 08:55

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

AEID

Adverse event

WORSENING DEPRESSION

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)

1 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 JAN 2021

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 (11)

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

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

US3042262

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

AEID

Adverse event

VIRAL SYNDROME OF  
UNKNOWN ETIOLOGY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

01 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

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	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 (13)

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

AEID	
Adverse event	L5 SLIPPED DISC
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)	04 JAN 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)	20 JAN 2021
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 (13)

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

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	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)	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

AEID	USA-US052-2021-MRNA-1273-P30 1000006
Adverse event	ACT OF SELF-HARM
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)	24 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)	24 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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"/>

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	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	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 28 Apr 2021 21:36:28

Generated On: 09 Jun 2021 14:55:45

---

PATIENT HAD SUICIDAL  
IDEATIONS AND BEGAN  
CUTTING HAND; PATIENT  
STOPPED WHEN SAW BLOOD.  
PATIENT DID NOT SEEK  
MEDICAL ATTENTION FOR  
CUT. PATIENT SAW PCP ONE  
WEEK AFTER INCIDENT AND  
WAS NOT HOSPITALIZED; PI  
DETERMINED THIS WAS AN  
ACT OF SELF-HARM, NOT AN  
ATTEMPT AT SUICIDE.

---

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)	

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

---

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 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication BUPROPION

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 300

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 21:36:29

Generated On: 09 Jun 2021 14:55:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication BUSPIRONE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:36:29

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Name of Medication METHYLPHENIDATE

Prophylaxis Yes ☐  
No ☒

Indication ATTENTION DEFICIT  
HYPERACTIVE DISORDER

Dose per administration 30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:36:29

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	Intraocular	<input type="radio"/>
	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 FEB 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 (4)

Data signed: (b) (4) 28 Apr 2021 21:36:29

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Name of Medication TRAZODONE

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 (4)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 FEB 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 (5)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication ALLEGRA D

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 120/60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 MAR 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 (6)

Data signed: (b) (4) 28 Apr 2021 21:36:29

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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 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication CLONIDINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration .05

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 21:36:29

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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 OCT 2019	
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 (8)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication FLUTICASON

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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 21:36:29

Generated On: 09 Jun 2021 14:55:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:36:29

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Name of Medication PROAIR

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 90

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 21:36:29

Generated On: 09 Jun 2021 14:55:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:36:29

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Name of Medication OLLY SLEEP

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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 FEB 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 21:36:29

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Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication BELLS PALSY

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 (11)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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)	08 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 JUL 2020	
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 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication VALACYCLOVIR

Prophylaxis Yes ☐  
No ☒

Indication BELLS PALSY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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)	08 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 JUL 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="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 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication BACLOFEN

Prophylaxis Yes ☐  
No ☒

Indication BELLS PALSY

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 (13)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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)	08 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 JUL 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication SOLICITED SYMPTOM-  
HEADACHES

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication DAYQUIL [ACETAMINOPHEN,  
DEXTROMETHORPHEN  
HYDROBROMIDE,  
PHENYLEPHRINE  
HYDROCHLORIDE]

Prophylaxis Yes ☐  
No ☒

Indication VIRAL SYNDROME OF  
UNKNOWN ETIOLOGY

Dose per administration 325/10/5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	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)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication DESVENLAFAXINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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)	9 NOV 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 (17)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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)	11 DEC 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 (18)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication L5 SLIPPED DISC

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 (18)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication	MEDICAL MARIJUANA CBD/THC
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	215/10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	08 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication	MEDICAL MARIJUANA CBD/THC
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	192.61/192.61
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)		08 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

Name of Medication	MEDICAL MARIJUANA CBD/THC
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	112/56
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

	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)	08 MAR 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"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:36:29

Generated On: 09 Jun 2021 14:55:45

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:55:45

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:55:45

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 ☐

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

SAEID	USA-US052-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

SAEID	USA-US052-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/MAR/2021 14:53
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



US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

SAEID	USA-US052-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/MAR/2021 15:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

SAEID	USA-US052-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/MAR/2021 10:12
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

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:36:30

Generated On: 09 Jun 2021 14:55:45

SAEID	USA-US052-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/MAR/2021 14:25
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

Audit

US3042262 (Prod: Meridian Clinical Research)

**US3042262**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:55:45**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'US3042262'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 20:04:22

US3042262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:04

US3042262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '20 AUG 2020'	RWS_ENDPOINT	20 Aug 2020 20:04:23
	ENDPOINT (b) (4)	

US3042262

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:04



**US3042262**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'SCRN'	(b) (4), (b) (6) System	21 Aug 2020 15:21:04

US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered (b) (6) 1997'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:25

US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '22'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:10
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:45**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'YEARS'	(b) (4), (b) (6) System	21 Aug 2020 15:21:10

**US3042262**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:45**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '22'	(b) (4), (b) (6) System	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Male (M)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:10

US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:10
	(b) (4)	

US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'I'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:10
	(b) (4)	



US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:10
	(b) (4)	

US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:10
	(b) (4)	

US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:10
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:45**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:10

**US3042262**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:45**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:10
	(b) (4)	

US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:10

**US3042262**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:55:45**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:10
	(b) (4)	

US3042262

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:55:45

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:10



US3042262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:45

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '20 Aug 2020'	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 20:32:45

**US3042262**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'Aug 2020'	(b) (4), (b) (6) System	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '2020'	(b) (4), (b) (6) System	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Amendment 2 (2)'	(b) (4) Jessica Knight (b) (4)	20 Aug 2020 20:32:45
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:45

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Jessica Knight (b) (4)	20 Aug 2020 20:32:45
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:55:45**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 20:32:45



US3042262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	RWS_ENDPOINT	20 Aug 2020 20:04:23
	ENDPOINT (b) (4)	

US3042262

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:55:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '1'	(b) (4), (b) (6) System	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	20 Aug 2020 20:32:30
	(b) (4)	

US3042262

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:55:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:18

US3042262

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:55:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(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)	21 Aug 2020 15:23:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:23:20
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:22:06
User entered 'DEPRESSION'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:28
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'UN UNK 2016'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:28

**US3042262**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:28

**US3042262**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:28



**US3042262**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:28

**US3042262**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:28

**US3042262**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'Jan 2016'	(b) (4), (b) (6) System	21 Aug 2020 15:21:28

**US3042262**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '2016'	(b) (4), (b) (6) System	21 Aug 2020 15:21:28

**US3042262**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:21:28

**US3042262**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:21:28

US3042262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:23:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:23:19
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:22:06
User entered 'SEASONAL ALLERGIES'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:42
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'UN UNK 2000'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:42



US3042262

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:42

**US3042262**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:42

**US3042262**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:42

**US3042262**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:42

**US3042262**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'Jan 2000'	(b) (4), (b) (6) System	21 Aug 2020 15:21:42

**US3042262**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '2000'	(b) (4), (b) (6) System	21 Aug 2020 15:21:42

**US3042262**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:21:42

**US3042262**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:21:42



US3042262

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:55:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:23:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:23:20
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:22:06
User entered 'ANXIETY'	Rylea Gulick (b) (4)	21 Aug 2020 15:21:49
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'UN UNK 2016'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:49

**US3042262**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:49

**US3042262**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:49

**US3042262**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:49

**US3042262**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:21:49

**US3042262**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'Jan 2016'	(b) (4), (b) (6) System	21 Aug 2020 15:21:49

**US3042262**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '2016'	(b) (4), (b) (6) System	21 Aug 2020 15:21:49



**US3042262**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:21:49

**US3042262**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:21:49

US3042262

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit hyperactivity disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:23:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:23:19
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:22:07
User entered 'ATTENTION DEFICIT HYPERACTIVE DISORDER'	Rylea Gulick (b) (4)	21 Aug 2020 15:22:02
	(b) (4)	

US3042262

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'UN UNK 2019'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:02

**US3042262**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:02

**US3042262**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:02

**US3042262**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:02

US3042262

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:55:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:02



**US3042262**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'Jan 2019'	(b) (4), (b) (6) System	21 Aug 2020 15:22:02

**US3042262**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '2019'	(b) (4), (b) (6) System	21 Aug 2020 15:22:02

**US3042262**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:02

**US3042262**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:02

US3042262

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(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)	21 Aug 2020 15:25:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:25:16
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:23:08
User entered 'INSOMNIA'	Rylea Gulick (b) (4)	21 Aug 2020 15:22:11
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'UN Feb 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:11

US3042262

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:11

**US3042262**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:55:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:11



**US3042262**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:11

US3042262

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:55:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:11

**US3042262**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'Feb 2020'	(b) (4), (b) (6) System	21 Aug 2020 15:22:11

**US3042262**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '2020'	(b) (4), (b) (6) System	21 Aug 2020 15:22:11

**US3042262**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:11

**US3042262**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:11

US3042262

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:25:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:25:16
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:23:08
User entered 'ASHTMA'	Rylea Gulick (b) (4)	21 Aug 2020 15:22:18
	(b) (4)	

US3042262

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'UN UNK 2005'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:18



US3042262

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:18

**US3042262**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:55:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:18

**US3042262**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:18

**US3042262**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:55:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:18

**US3042262**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'Jan 2005'	(b) (4), (b) (6) System	21 Aug 2020 15:22:18

**US3042262**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '2005'	(b) (4), (b) (6) System	21 Aug 2020 15:22:18

**US3042262**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:18

**US3042262**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:18



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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:55:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:25:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:25:15
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:23:08
User entered 'SEVERE OBESITY'	Rylea Gulick (b) (4)	21 Aug 2020 15:22:30
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'UN UNK 2010'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:30

**US3042262**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:30

**US3042262**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:30

**US3042262**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:30

**US3042262**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:30

**US3042262**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'Jan 2010'	(b) (4), (b) (6) System	21 Aug 2020 15:22:30

**US3042262**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '2010'	(b) (4), (b) (6) System	21 Aug 2020 15:22:30



**US3042262**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:30

**US3042262**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:30

US3042262

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Facial cranial nerve disorders, PT: Facial paralysis, LLT: Bell's palsy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:25:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 15:25:16
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:23:11
User entered 'BELLS PALSY'	Rylea Gulick (b) (4)	21 Aug 2020 15:22:43
	(b) (4)	

**US3042262**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'UN Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:43

US3042262

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:43

**US3042262**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:55:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:43

US3042262

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:43

US3042262

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:55:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:22:43



**US3042262**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'Jul 2020'	(b) (4), (b) (6) System	21 Aug 2020 15:22:43

**US3042262**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '2020'	(b) (4), (b) (6) System	21 Aug 2020 15:22:43

**US3042262**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:43

**US3042262**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:22:43

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:09

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '20 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:09

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '14:09'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:09

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered '20 Aug 2020 14:09'	(b) (4), (b) (6) System	21 Aug 2020 15:23:09



US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '185.4' cm	Rylea Gulick (b) (4)	21 Aug 2020 15:23:09
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '140.5' kg	Rylea Gulick (b) (4)	21 Aug 2020 15:23:09
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
Amendment Manager: User entered '40.87492'	(b) (4), (b) (6)	
User entered '40.9'	System	17 Sep 2020 00:17:03
DataPoint set to visible.	System	21 Aug 2020 15:23:09
	System	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	21 Aug 2020 15:23:09
DataPoint set to visible.	System	20 Aug 2020 20:32:45

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensiz (b) (4)	28 Apr 2021 21:36:34
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)	09 Oct 2020 07:27:17
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 14:40:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:40:02
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)	08 Oct 2020 08:57:54
User entered '37.1' C	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:09

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:40:02
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:09
	(b) (4)	

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 15:23:09
	(b) (4)	

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:40:02
change Data Entry Error	(b) (4)	
User entered '90'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:09
	(b) (4)	



**US3042262**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 15:23:09

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:40:02
change Data Entry Error	(b) (4)	
User entered '12'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:09
	(b) (4)	

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 15:23:09

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:40:02
change Data Entry Error	(b) (4)	
User entered '130'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:09
	(b) (4)	

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 15:23:09

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:40:02
change Data Entry Error	(b) (4)	
User entered '83'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:09
	(b) (4)	

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 15:23:09

US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:03:11



US3042262

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:03:11

**US3042262**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:55:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:13

US3042262

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '20 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:13

US3042262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:45

**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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

US3042262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:45

**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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

US3042262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:45

**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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

US3042262

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:45

**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 06:03:11
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:26
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26



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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:26
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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Folder: Screening

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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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:26
	(b) (4)	

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 15:23:26
	(b) (4)	



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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:26
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:45

**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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:45

[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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:55:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:26
	(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 06:03:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:26



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Jessica Knight (b) (4)	20 Aug 2020 20:33:03
	(b) (4)	

**US3042262**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '20 Aug 2020'	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 20:33:03

US3042262

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[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 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Clinic (Clinic)'	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 20:33:03

**US3042262**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'VISIT1'	(b) (4), (b) (6) System	20 Aug 2020 20:33:03

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:38

US3042262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:45

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 06:02:01
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:02:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 20:04:38
User entered '144563' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:38

US3042262

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:55:45

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 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:39



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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 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:39
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:23:39

**US3042262**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:55:45**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	21 Aug 2020 15:23:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	21 Aug 2020 15:23:39
	(b) (4)	

US3042262

Folder: Visit 1 Day 1

Form: Randomization

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Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:36:34
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'ENTRY UPDATED ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:29:28
User entered 'No (N)'	Rylea Gulick (b) (4)	29 Oct 2020 17:50:14
	(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 15:01:33
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:30
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:51:22

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:36:34
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)	29 Oct 2020 07:24:42
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)	28 Oct 2020 19:48:52
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)	28 Oct 2020 19:48:49
	(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)	28 Oct 2020 06:57:11
User entered '185.4' cm	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:48:49
change Data Entry Error	(b) (4)	
User entered '140.5' kg	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
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) (6)	29 Oct 2020 07:24:42
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)	28 Oct 2020 19:48:52
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)	28 Oct 2020 19:48:49
	(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)	28 Oct 2020 06:57:11
User entered '185.4' cm	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:48:49
change Data Entry Error	(b) (4)	
User entered '140.5' kg	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '20 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '14:09'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered '20 Aug 2020 14:09'	(b) (4), (b) (6) System	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '37.1' C	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:24:19



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:24:19

US3042262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '90'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 15:24:19

US3042262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '12'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 15:24:19

US3042262

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '130'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '83'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:45

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
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) (6)	29 Oct 2020 07:24:42
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)	28 Oct 2020 19:48:52
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)	28 Oct 2020 19:48:49
	(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)	28 Oct 2020 06:57:11
User entered '185.4' cm	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:55:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:48:49
change Data Entry Error	(b) (4)	
User entered '140.5' kg	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '20 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '15:48'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered '20 Aug 2020 15:48'	(b) (4), (b) (6) System	21 Aug 2020 15:24:19



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '37.1' C	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '79'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 18:36:50
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 18:36:50
User entered '14' reason for change: Data Entry Error	Rylea Gulick (b) (4)	04 Sep 2020 18:36:50
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 15:24:19
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'breaths/min'	(b) (4), (b) (6)	
	System	04 Sep 2020 18:36:50
User entered empty.	System	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '128'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '89'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 15:24:19

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	21 Aug 2020 15:24:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '20 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:24:46

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Jessica Knight (b) (4)	20 Aug 2020 20:33:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jessica Knight (b) (4)	20 Aug 2020 20:33:51
	(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 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jessica Knight (b) (4)	20 Aug 2020 20:33:51
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '20 Aug 2020'	Jessica Knight (b) (4)	20 Aug 2020 20:33:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '15:16'	(b) (4) Jessica Knight (b) (4)	20 Aug 2020 20:33:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered '20 Aug 2020 15:16'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Jessica Knight (b) (4)	20 Aug 2020 20:33:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'ONCE'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:54
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '20 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:24:54

US3042262

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '14:58'	Rylea Gulick (b) (4)	21 Aug 2020 15:24:54
	(b) (4)	

**US3042262**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered '20 Aug 2020 14:58'	(b) (4), (b) (6) System	21 Aug 2020 15:24:54

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:55:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered '20 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	21 Aug 2020 15:25:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '14:44'	Rylea Gulick (b) (4)	21 Aug 2020 15:25:15
	(b) (4)	

**US3042262**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered '20 Aug 2020 14:44'	(b) (4), (b) (6) System	21 Aug 2020 15:25:15



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	21 Aug 2020 15:25:15
	(b) (4)	

US3042262

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 15:25:15
	(b) (4)	

**US3042262**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 15:25:15

US3042262

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 15:25:17
	(b) (4)	

US3042262

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:47
User entered 'I'	(b) (4), (b) (6) System	21 Aug 2020 15:25:17

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:48:21', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '52253aaf-73b3-47ce-8e51-5c6fd7d0b4ec'	(b) (4), (b) (6)	
	System	20 Aug 2020 20:48:40
User entered 'Yes (Y)'	System	20 Aug 2020 20:48:40



US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:48:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '52253aaf-73b3-47ce-8e51-5c6fd7d0b4ec' User entered '98.8'	(b) (4), (b) (6) System	20 Aug 2020 20:48:40
	System	20 Aug 2020 20:48:40

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:48:30', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '52253aaf-73b3-47ce-8e51-5c6fd7d0b4ec'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 20:48:40

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:48:36', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '52253aaf-73b3-47ce-8e51-5c6fd7d0b4ec' User entered '20 Aug 2020 15:48'	(b) (4), (b) (6) System	20 Aug 2020 20:48:40
	System	20 Aug 2020 20:48:40

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Aug 2020 15:36'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Aug 2020 18:06'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:55:38', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48c65c0f-d48a-4e47-ba97-26dfd0ed4a24' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 01:55:58
	System	21 Aug 2020 01:55:58

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:55:46', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48c65c0f-d48a-4e47-ba97-26dfd0ed4a24' User entered '97.9'	(b) (4), (b) (6) System	21 Aug 2020 01:55:58
	System	21 Aug 2020 01:55:58



US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:55:51', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48c65c0f-d48a-4e47-ba97-26dfd0ed4a24'	(b) (4), (b) (6)	
	System	21 Aug 2020 01:55:58
User entered 'No (N)'	System	21 Aug 2020 01:55:58

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:55:54', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48c65c0f-d48a-4e47-ba97-26dfd0ed4a24' User entered '20 Aug 2020 20:55'	(b) (4), (b) (6) System	21 Aug 2020 01:55:58
	System	21 Aug 2020 01:55:58

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Aug 2020 19:01'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 2'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:27', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '9b897eb1-bea9-4a01-af93-7444891f6090' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 03:18:39
	System	22 Aug 2020 03:18:39

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:31', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '9b897eb1-bea9-4a01-af93-7444891f6090' User entered '98.6'	(b) (4), (b) (6) System	22 Aug 2020 03:18:39
	System	22 Aug 2020 03:18:39

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:34', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '9b897eb1-bea9-4a01-af93-7444891f6090'	(b) (4), (b) (6)	
User entered 'No (N)'	System	22 Aug 2020 03:18:39



**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:37', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '9b897eb1-bea9-4a01-af93-7444891f6090' User entered '21 Aug 2020 21:18'	(b) (4), (b) (6) System	22 Aug 2020 03:18:39
	System	22 Aug 2020 03:18:39

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 3'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:00:50', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8bb9ffe6-8478-4ba9-9cec-a9c82a7a5b61' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:02
	System	23 Aug 2020 06:01:02

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:00:53', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8bb9ffe6-8478-4ba9-9cec-a9c82a7a5b61' User entered '98.2'	(b) (4), (b) (6) System	23 Aug 2020 06:01:02
	System	23 Aug 2020 06:01:02

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:00:56', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8bb9ffe6-8478-4ba9-9cec-a9c82a7a5b61' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:02
	System	23 Aug 2020 06:01:02

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:00:59', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8bb9ffe6-8478-4ba9-9cec-a9c82a7a5b61' User entered '23 Aug 2020 00:00'	(b) (4), (b) (6) System	23 Aug 2020 06:01:02
	System	23 Aug 2020 06:01:02



US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 4'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c4a41016-800d-4720-b1b0-d5e742131448' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Aug 2020 00:34:19
	System	24 Aug 2020 00:34:19

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:13', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c4a41016-800d-4720-b1b0-d5e742131448' User entered '97.9'	(b) (4), (b) (6) System	24 Aug 2020 00:34:19
	System	24 Aug 2020 00:34:19

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:15', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c4a41016-800d-4720-b1b0-d5e742131448'	(b) (4), (b) (6)	
User entered 'No (N)'	System	24 Aug 2020 00:34:19

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:17', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c4a41016-800d-4720-b1b0-d5e742131448' User entered '23 Aug 2020 19:34'	(b) (4), (b) (6) System	24 Aug 2020 00:34:19
	System	24 Aug 2020 00:34:19

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51



US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 5'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:04', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'ce778fc3-1ab5-4b96-9354-7a7dcf4eca06'	(b) (4), (b) (6)	
	System	24 Aug 2020 23:36:22
User entered 'Yes (Y)'	System	24 Aug 2020 23:36:22

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'ce778fc3-1ab5-4b96-9354-7a7dcf4eca06' User entered '98.1'	(b) (4), (b) (6) System	24 Aug 2020 23:36:22
	System	24 Aug 2020 23:36:22

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:14', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'ce778fc3-1ab5-4b96-9354-7a7dcf4eca06'	(b) (4), (b) (6)	
User entered 'No (N)'	System	24 Aug 2020 23:36:22

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:19', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'ce778fc3-1ab5-4b96-9354-7a7dcf4eca06' User entered '24 Aug 2020 18:36'	(b) (4), (b) (6) System	24 Aug 2020 23:36:22
	System	24 Aug 2020 23:36:22

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51



US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 6'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:31:46', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '3109883b-a680-4604-9490-65d6bb1d17d2' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Aug 2020 12:31:59
	System	26 Aug 2020 12:31:59

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:31:50', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '3109883b-a680-4604-9490-65d6bb1d17d2' User entered '98.0'	(b) (4), (b) (6) System	26 Aug 2020 12:31:59
	System	26 Aug 2020 12:31:59

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:31:54', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '3109883b-a680-4604-9490-65d6bb1d17d2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Aug 2020 12:31:59

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:31:56', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '3109883b-a680-4604-9490-65d6bb1d17d2' User entered '26 Aug 2020 07:31'	(b) (4), (b) (6) System	26 Aug 2020 12:31:59
	System	26 Aug 2020 12:31:59

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 7'	System	20 Aug 2020 20:33:51



US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:32:52', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '86785dcb-17d4-48b1-b5dc-723f4f999a59' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:02
	System	27 Aug 2020 11:33:02

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:32:56', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '86785dcb-17d4-48b1-b5dc-723f4f999a59' User entered '97.6'	(b) (4), (b) (6) System	27 Aug 2020 11:33:02
	System	27 Aug 2020 11:33:02

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:32:58', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '86785dcb-17d4-48b1-b5dc-723f4f999a59'	(b) (4), (b) (6)	
User entered 'No (N)'	System	27 Aug 2020 11:33:02

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:01', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '86785dcb-17d4-48b1-b5dc-723f4f999a59' User entered '27 Aug 2020 06:33'	(b) (4), (b) (6) System	27 Aug 2020 11:33:02
	System	27 Aug 2020 11:33:02

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:48:44', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'a18cf93e-16eb-4ba1-a87b-a96cc8ba13fd' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:09
	System	20 Aug 2020 20:49:09



US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:48:46', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'a18cf93e-16eb-4ba1-a87b-a96cc8ba13fd' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:09
	System	20 Aug 2020 20:49:09

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:48:51', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'a18cf93e-16eb-4ba1-a87b-a96cc8ba13fd' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:09
	System	20 Aug 2020 20:49:09

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:48:58', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'a18cf93e-16eb-4ba1-a87b-a96cc8ba13fd' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:09
	System	20 Aug 2020 20:49:09

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:49:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'a18cf93e-16eb-4ba1-a87b-a96cc8ba13fd' User entered '20 Aug 2020 15:49'	(b) (4), (b) (6) System	20 Aug 2020 20:49:09
	System	20 Aug 2020 20:49:09

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Aug 2020 15:36'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Aug 2020 18:06'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:56:27', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'cf440883-9bc7-461d-9c6f-0cf6c52c2ab7'	(b) (4), (b) (6)	21 Aug 2020 01:57:06
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 01:57:06



US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:56:33', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'cf440883-9bc7-461d-9c6f-0cf6c52c2ab7'	(b) (4), (b) (6)	
	System	21 Aug 2020 01:57:06
User entered 'No (N)'	System	21 Aug 2020 01:57:06

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:56:40', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'cf440883-9bc7-461d-9c6f-0cf6c52c2ab7'	(b) (4), (b) (6)	
	System	21 Aug 2020 01:57:06
User entered 'No (N)'	System	21 Aug 2020 01:57:06

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:56:51', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'cf440883-9bc7-461d-9c6f-0cf6c52c2ab7'	(b) (4), (b) (6)	21 Aug 2020 01:57:06
User entered 'None (1)'	System	21 Aug 2020 01:57:06

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:57:01', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'cf440883-9bc7-461d-9c6f-0cf6c52c2ab7' User entered '20 Aug 2020 20:57'	(b) (4), (b) (6) System	21 Aug 2020 01:57:06
	System	21 Aug 2020 01:57:06

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Aug 2020 19:01'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 2'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:01', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '1a648ba8-fc90-49dc-b5b0-216801ed7635'	(b) (4), (b) (6)	22 Aug 2020 03:18:25
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 03:18:25



US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:04', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '1a648ba8-fc90-49dc-b5b0-216801ed7635' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 03:18:25
	System	22 Aug 2020 03:18:25

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:15', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '1a648ba8-fc90-49dc-b5b0-216801ed7635' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 03:18:25
	System	22 Aug 2020 03:18:25

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:18', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '1a648ba8-fc90-49dc-b5b0-216801ed7635' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 03:18:25
	System	22 Aug 2020 03:18:25

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:22', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '1a648ba8-fc90-49dc-b5b0-216801ed7635' User entered '21 Aug 2020 21:18'	(b) (4), (b) (6) System	22 Aug 2020 03:18:25
	System	22 Aug 2020 03:18:25

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 3'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '34adc653-f006-4fe2-951e-9b48db158f57'	(b) (4), (b) (6)	23 Aug 2020 06:01:23
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 06:01:23



US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '34adc653-f006-4fe2-951e-9b48db158f57' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:23
	System	23 Aug 2020 06:01:23

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:08', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '34adc653-f006-4fe2-951e-9b48db158f57' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:23
	System	23 Aug 2020 06:01:23

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:11', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '34adc653-f006-4fe2-951e-9b48db158f57'	(b) (4), (b) (6)	23 Aug 2020 06:01:23
User entered 'None (1)'	System	23 Aug 2020 06:01:23

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:21', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '34adc653-f006-4fe2-951e-9b48db158f57' User entered '23 Aug 2020 00:01'	(b) (4), (b) (6) System	23 Aug 2020 06:01:23
	System	23 Aug 2020 06:01:23

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 4'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:21', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c49840e2-30cc-4b50-a9ec-2d0cf2a8f10d' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 00:34:37
	System	24 Aug 2020 00:34:37



US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:23', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c49840e2-30cc-4b50-a9ec-2d0cf2a8f10d' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 00:34:37
	System	24 Aug 2020 00:34:37

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c49840e2-30cc-4b50-a9ec-2d0cf2a8f10d' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 00:34:37
	System	24 Aug 2020 00:34:37

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:30', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c49840e2-30cc-4b50-a9ec-2d0cf2a8f10d' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 00:34:37
	System	24 Aug 2020 00:34:37

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:34', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c49840e2-30cc-4b50-a9ec-2d0cf2a8f10d' User entered '23 Aug 2020 19:34'	(b) (4), (b) (6) System	24 Aug 2020 00:34:37
	System	24 Aug 2020 00:34:37

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 5'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:25', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'ff140102-b4c3-4f19-83d9-970b5e10e243' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 23:36:43
	System	24 Aug 2020 23:36:43



US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:27', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'ff140102-b4c3-4f19-83d9-970b5e10e243'	(b) (4), (b) (6)	
User entered 'No (N)'	System	24 Aug 2020 23:36:43

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:34', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'ff140102-b4c3-4f19-83d9-970b5e10e243' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 23:36:43
	System	24 Aug 2020 23:36:43

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:36', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'ff140102-b4c3-4f19-83d9-970b5e10e243' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 23:36:43
	System	24 Aug 2020 23:36:43

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:37', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'ff140102-b4c3-4f19-83d9-970b5e10e243' User entered '24 Aug 2020 18:36'	(b) (4), (b) (6) System	24 Aug 2020 23:36:43
	System	24 Aug 2020 23:36:43

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 6'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:02', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '439d8fd0-7f46-49d1-85b6-69792dac0ffb' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:15
	System	26 Aug 2020 12:32:15



US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '439d8fd0-7f46-49d1-85b6-69792dac0ffb' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:15
	System	26 Aug 2020 12:32:15

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '439d8fd0-7f46-49d1-85b6-69792dac0ffb' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:15
	System	26 Aug 2020 12:32:15

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:09', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '439d8fd0-7f46-49d1-85b6-69792dac0ffb' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:15
	System	26 Aug 2020 12:32:15

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:11', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '439d8fd0-7f46-49d1-85b6-69792dac0ffb' User entered '26 Aug 2020 07:32'	(b) (4), (b) (6) System	26 Aug 2020 12:32:15
	System	26 Aug 2020 12:32:15

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 7'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:03', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e474e953-fd1d-453c-9a24-74e7b26f1011' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:16
	System	27 Aug 2020 11:33:16



US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e474e953-fd1d-453c-9a24-74e7b26f1011' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:16
	System	27 Aug 2020 11:33:16

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e474e953-fd1d-453c-9a24-74e7b26f1011' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:16
	System	27 Aug 2020 11:33:16

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:09', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e474e953-fd1d-453c-9a24-74e7b26f1011' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:16
	System	27 Aug 2020 11:33:16

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:11', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e474e953-fd1d-453c-9a24-74e7b26f1011' User entered '27 Aug 2020 06:33'	(b) (4), (b) (6) System	27 Aug 2020 11:33:16
	System	27 Aug 2020 11:33:16

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:49:12', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '82faf8ef-8403-44d3-aeb9-10499776c700' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:49
	System	20 Aug 2020 20:49:49



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:49:16', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '82faf8ef-8403-44d3-aeb9-10499776c700' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:49
	System	20 Aug 2020 20:49:49

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:49:20', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '82faf8ef-8403-44d3-aeb9-10499776c700' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:49
	System	20 Aug 2020 20:49:49

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:49:23', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '82faf8ef-8403-44d3-aeb9-10499776c700' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:49
	System	20 Aug 2020 20:49:49

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:49:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '82faf8ef-8403-44d3-aeb9-10499776c700' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:49
	System	20 Aug 2020 20:49:49

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:49:28', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '82faf8ef-8403-44d3-aeb9-10499776c700' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:49
	System	20 Aug 2020 20:49:49

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:49:44', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '82faf8ef-8403-44d3-aeb9-10499776c700' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 20:49:49
	System	20 Aug 2020 20:49:49

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T15:49:47', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '82faf8ef-8403-44d3-aeb9-10499776c700'	(b) (4), (b) (6)	
	System	20 Aug 2020 20:49:49
User entered '20 Aug 2020 15:49'	System	20 Aug 2020 20:49:49

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Aug 2020 15:36'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Aug 2020 18:06'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:57:13', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21ce0b85-e056-4620-9cda-12a96b86f4f7' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 01:57:43
	System	21 Aug 2020 01:57:43

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:57:17', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21ce0b85-e056-4620-9cda-12a96b86f4f7' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 01:57:43
	System	21 Aug 2020 01:57:43

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:57:21', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21ce0b85-e056-4620-9cda-12a96b86f4f7' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 01:57:43
	System	21 Aug 2020 01:57:43

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:57:25', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21ce0b85-e056-4620-9cda-12a96b86f4f7' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 01:57:43
	System	21 Aug 2020 01:57:43

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:57:29', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21ce0b85-e056-4620-9cda-12a96b86f4f7' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 01:57:43
	System	21 Aug 2020 01:57:43

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:57:32', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21ce0b85-e056-4620-9cda-12a96b86f4f7' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 01:57:43
	System	21 Aug 2020 01:57:43



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:57:40', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21ce0b85-e056-4620-9cda-12a96b86f4f7' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 01:57:43
	System	21 Aug 2020 01:57:43

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-20T20:57:42', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21ce0b85-e056-4620-9cda-12a96b86f4f7' User entered '20 Aug 2020 20:57'	(b) (4), (b) (6) System	21 Aug 2020 01:57:43
	System	21 Aug 2020 01:57:43

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Aug 2020 19:01'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 2'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:41', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48ec9ddd-ad50-4910-b2cf-daef660fadaa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 03:19:08
	System	22 Aug 2020 03:19:08

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:43', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48ec9ddd-ad50-4910-b2cf-daef660fadaa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 03:19:08
	System	22 Aug 2020 03:19:08

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:44', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48ec9ddd-ad50-4910-b2cf-daef660fadaa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 03:19:08
	System	22 Aug 2020 03:19:08



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:46', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48ec9ddd-ad50-4910-b2cf-daef660fadaa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 03:19:08
	System	22 Aug 2020 03:19:08

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:53', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48ec9ddd-ad50-4910-b2cf-daef660fadaa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 03:19:08
	System	22 Aug 2020 03:19:08

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:18:58', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48ec9ddd-ad50-4910-b2cf-daef660fadaa' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 03:19:08
	System	22 Aug 2020 03:19:08

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:19:01', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48ec9ddd-ad50-4910-b2cf-daef660fadaa' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 03:19:08
	System	22 Aug 2020 03:19:08

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-21T21:19:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '48ec9ddd-ad50-4910-b2cf-daef660fadaa' User entered '21 Aug 2020 21:19'	(b) (4), (b) (6) System	22 Aug 2020 03:19:08
	System	22 Aug 2020 03:19:08

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 3'	System	20 Aug 2020 20:33:51



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:29', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2faf37d9-182c-466b-963a-3ce06dc3f368' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:41
	System	23 Aug 2020 06:01:41

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:30', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2faf37d9-182c-466b-963a-3ce06dc3f368' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:41
	System	23 Aug 2020 06:01:41

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:32', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2faf37d9-182c-466b-963a-3ce06dc3f368' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:41
	System	23 Aug 2020 06:01:41

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:33', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2faf37d9-182c-466b-963a-3ce06dc3f368' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:41
	System	23 Aug 2020 06:01:41

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:34', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2faf37d9-182c-466b-963a-3ce06dc3f368' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:41
	System	23 Aug 2020 06:01:41

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:55:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:36', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2faf37d9-182c-466b-963a-3ce06dc3f368' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:41
	System	23 Aug 2020 06:01:41

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:38', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2faf37d9-182c-466b-963a-3ce06dc3f368' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 06:01:41
	System	23 Aug 2020 06:01:41

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T00:01:40', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2faf37d9-182c-466b-963a-3ce06dc3f368' User entered '23 Aug 2020 00:01'	(b) (4), (b) (6) System	23 Aug 2020 06:01:41
	System	23 Aug 2020 06:01:41



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 4'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:37', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '61161ced-390f-4d10-98af-11a53b3a0fd9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 00:35:09
	System	24 Aug 2020 00:35:09

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:39', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '61161ced-390f-4d10-98af-11a53b3a0fd9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 00:35:09
	System	24 Aug 2020 00:35:09

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:42', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '61161ced-390f-4d10-98af-11a53b3a0fd9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 00:35:09
	System	24 Aug 2020 00:35:09

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:44', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '61161ced-390f-4d10-98af-11a53b3a0fd9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 00:35:09
	System	24 Aug 2020 00:35:09

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:34:55', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '61161ced-390f-4d10-98af-11a53b3a0fd9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 00:35:09
	System	24 Aug 2020 00:35:09



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:35:01', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '61161ced-390f-4d10-98af-11a53b3a0fd9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 00:35:09
	System	24 Aug 2020 00:35:09

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:35:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '61161ced-390f-4d10-98af-11a53b3a0fd9' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 00:35:09
	System	24 Aug 2020 00:35:09

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-23T19:35:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '61161ced-390f-4d10-98af-11a53b3a0fd9' User entered '23 Aug 2020 19:35'	(b) (4), (b) (6) System	24 Aug 2020 00:35:09
	System	24 Aug 2020 00:35:09

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 5'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:41', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5816612a-667d-47e8-aa09-7cacd4558a9c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:37:05
	System	24 Aug 2020 23:37:05

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:42', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5816612a-667d-47e8-aa09-7cacd4558a9c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:37:05
	System	24 Aug 2020 23:37:05



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:43', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5816612a-667d-47e8-aa09-7cacd4558a9c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:37:05
	System	24 Aug 2020 23:37:05

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:44', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5816612a-667d-47e8-aa09-7cacd4558a9c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:37:05
	System	24 Aug 2020 23:37:05

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:46', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5816612a-667d-47e8-aa09-7cacd4558a9c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:37:05
	System	24 Aug 2020 23:37:05

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:47', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5816612a-667d-47e8-aa09-7cacd4558a9c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:37:05
	System	24 Aug 2020 23:37:05

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:49', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5816612a-667d-47e8-aa09-7cacd4558a9c' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 23:37:05
	System	24 Aug 2020 23:37:05

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-24T18:36:54', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5816612a-667d-47e8-aa09-7cacd4558a9c' User entered '24 Aug 2020 18:36'	(b) (4), (b) (6) System	24 Aug 2020 23:37:05
	System	24 Aug 2020 23:37:05

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 6'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:16', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '67ab1d0e-c478-4693-9341-0cc3eb0fd3c2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:38
	System	26 Aug 2020 12:32:38

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:18', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '67ab1d0e-c478-4693-9341-0cc3eb0fd3c2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:38
	System	26 Aug 2020 12:32:38

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:22', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '67ab1d0e-c478-4693-9341-0cc3eb0fd3c2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:38
	System	26 Aug 2020 12:32:38

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:23', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '67ab1d0e-c478-4693-9341-0cc3eb0fd3c2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:38
	System	26 Aug 2020 12:32:38

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:25', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '67ab1d0e-c478-4693-9341-0cc3eb0fd3c2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:38
	System	26 Aug 2020 12:32:38

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:27', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '67ab1d0e-c478-4693-9341-0cc3eb0fd3c2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:38
	System	26 Aug 2020 12:32:38

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:30', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '67ab1d0e-c478-4693-9341-0cc3eb0fd3c2' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 12:32:38
	System	26 Aug 2020 12:32:38



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-26T07:32:32', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '67ab1d0e-c478-4693-9341-0cc3eb0fd3c2' User entered '26 Aug 2020 07:32'	(b) (4), (b) (6) System	26 Aug 2020 12:32:38
	System	26 Aug 2020 12:32:38

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 7'	System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:14', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5e7abf6b-dbf0-418f-8d42-8b76d81aeafd' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:27
	System	27 Aug 2020 11:33:27

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:16', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5e7abf6b-dbf0-418f-8d42-8b76d81aeafd' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:27
	System	27 Aug 2020 11:33:27

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:18', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5e7abf6b-dbf0-418f-8d42-8b76d81aeafd' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:27
	System	27 Aug 2020 11:33:27

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:19', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5e7abf6b-dbf0-418f-8d42-8b76d81aeafd' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:27
	System	27 Aug 2020 11:33:27



US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:20', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5e7abf6b-dbf0-418f-8d42-8b76d81aeafd' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:27
	System	27 Aug 2020 11:33:27

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:22', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5e7abf6b-dbf0-418f-8d42-8b76d81aeafd' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:27
	System	27 Aug 2020 11:33:27

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:24', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5e7abf6b-dbf0-418f-8d42-8b76d81aeafd' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 11:33:27
	System	27 Aug 2020 11:33:27

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19810D07-CC53-4783-B3D9-97D4CCC120EF)', Time: '2020-08-27T06:33:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5e7abf6b-dbf0-418f-8d42-8b76d81aeafd' User entered '27 Aug 2020 06:33'	(b) (4), (b) (6) System	27 Aug 2020 11:33:27
	System	27 Aug 2020 11:33:27

**US3042262**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

US3042262

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 20:33:51

**US3042262**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 22:11:31

US3042262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered '27 Aug 2020'	Rylea Gulick (b) (4)	03 Sep 2020 22:11:31



**US3042262**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	03 Sep 2020 22:11:31

US3042262

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered empty.	Rylea Gulick (b) (4)	03 Sep 2020 22:11:31

US3042262

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	03 Sep 2020 22:11:33

US3042262

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User entered 'I'	System	03 Sep 2020 22:11:33

**US3042262**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:15
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	03 Sep 2020 22:11:40

**US3042262**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:15
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered '03 Sep 2020'	Rylea Gulick (b) (4)	03 Sep 2020 22:11:40

**US3042262**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:15
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	03 Sep 2020 22:11:40

US3042262

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:15
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	Rylea Gulick (b) (4)	03 Sep 2020 22:11:40



US3042262

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:15
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	03 Sep 2020 22:11:42

US3042262

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:15
User entered 'I'	System	03 Sep 2020 22:11:42

**US3042262**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:27
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4)	12 Sep 2020 18:56:57

**US3042262**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:27
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '12 Sep 2020'	(b) (4) Jamie Thompson (b) (4)	12 Sep 2020 18:56:57
	(b) (4)	

US3042262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:27
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Thompson (b) (4)	12 Sep 2020 18:56:57

US3042262

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:27
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	Jamie Thompson (b) (4)	12 Sep 2020 18:56:57

US3042262

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:27
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4)	12 Sep 2020 18:57:01

**US3042262**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:27
User entered 'I'	System	12 Sep 2020 18:57:01



US3042262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 22:51:50
	(b) (4)	

**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '17 Sep 2020'	Rylea Gulick (b) (4)	17 Sep 2020 22:51:50
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[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 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	17 Sep 2020 22:51:50
	(b) (4)	

**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'VISIT2'	(b) (4), (b) (6) System	17 Sep 2020 22:51:50

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '17 Sep 2020'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '15:15'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	



US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered '17 Sep 2020 15:15'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '37.1' C	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:55:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '92'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'bpm'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53



US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '128'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'mmHg'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '76'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'mmHg'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	17 Sep 2020 22:52:53

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '17 Sep 2020'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16:45'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	



**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered '17 Sep 2020 16:45'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '36.9' C	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '50'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'bpm'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '12'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53



US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '120'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'mmHg'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53

US3042262

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '88'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:53
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'mmHg'	(b) (4), (b) (6) System	17 Sep 2020 22:52:53

US3042262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:57
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '17 Sep 2020'	Rylea Gulick (b) (4)	17 Sep 2020 22:52:57
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 21:28:40
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	17 Sep 2020 21:28:40
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

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 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	17 Sep 2020 21:28:40
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '17 Sep 2020'	Rylea Gulick (b) (4)	17 Sep 2020 21:28:40
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16:08'	Rylea Gulick (b) (4)	17 Sep 2020 21:28:40
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered '17 Sep 2020 16:08'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4)	17 Sep 2020 21:28:40
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'ONCE'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:55:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 22:53:03
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '17 Sep 2020'	Rylea Gulick (b) (4)	17 Sep 2020 22:53:03
	(b) (4)	

**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:45**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '15:24'	Rylea Gulick (b) (4)	17 Sep 2020 22:53:03
	(b) (4)	

**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered '17 Sep 2020 15:24'	(b) (4), (b) (6) System	17 Sep 2020 22:53:03

US3042262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:55:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '17 Sep 2020'	Rylea Gulick (b) (4)	17 Sep 2020 22:53:09
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	17 Sep 2020 22:53:09

US3042262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 22:53:09
	(b) (4)	

**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '15:29'	Rylea Gulick (b) (4)	17 Sep 2020 22:53:09
	(b) (4)	



**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered '17 Sep 2020 15:29'	(b) (4), (b) (6) System	17 Sep 2020 22:53:09

US3042262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	17 Sep 2020 22:53:09

US3042262

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	17 Sep 2020 22:53:09
	(b) (4)	

**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	17 Sep 2020 22:53:09
	(b) (4)	

**US3042262**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered empty.	(b) (4), (b) (6) System	17 Sep 2020 22:53:09

US3042262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 22:53:10
	(b) (4)	

US3042262

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:07
User entered '1'	(b) (4), (b) (6) System	17 Sep 2020 22:53:10

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:45:19', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '9e133093-f1d4-4668-8f61-2cc5d3b6a12a'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	17 Sep 2020 21:45:32

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:45:23', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '9e133093-f1d4-4668-8f61-2cc5d3b6a12a' User entered '98.7'	(b) (4), (b) (6) System	17 Sep 2020 21:45:32
	System	17 Sep 2020 21:45:32

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:45:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '9e133093-f1d4-4668-8f61-2cc5d3b6a12a'	(b) (4), (b) (6)	
	System	17 Sep 2020 21:45:32
User entered 'No (N)'	System	17 Sep 2020 21:45:32

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:45:29', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '9e133093-f1d4-4668-8f61-2cc5d3b6a12a'	(b) (4), (b) (6) System	17 Sep 2020 21:45:32
User entered '17 Sep 2020 16:45'	System	17 Sep 2020 21:45:32

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '17 Sep 2020 16:28'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '17 Sep 2020 18:58'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:53:22', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '502e5b4d-3891-4068-b18e-b54a20f1cb78'	(b) (4), (b) (6) System	18 Sep 2020 00:53:39
User entered 'Yes (Y)'	System	18 Sep 2020 00:53:39



US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:53:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '502e5b4d-3891-4068-b18e-b54a20f1cb78'	(b) (4), (b) (6) System	18 Sep 2020 00:53:39
User entered '97.6'	System	18 Sep 2020 00:53:39

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:53:30', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '502e5b4d-3891-4068-b18e-b54a20f1cb78'	(b) (4), (b) (6) System	18 Sep 2020 00:53:39
User entered 'No (N)'	System	18 Sep 2020 00:53:39

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:53:35', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '502e5b4d-3891-4068-b18e-b54a20f1cb78'	(b) (4), (b) (6) System	18 Sep 2020 00:53:39
User entered '17 Sep 2020 19:53'	System	18 Sep 2020 00:53:39

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '17 Sep 2020 19:53'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 2'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:01:32', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '56d2e074-2b70-4135-a489-10e32982e2ed'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	18 Sep 2020 17:02:30

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:01:36', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '56d2e074-2b70-4135-a489-10e32982e2ed' User entered '98.4'	(b) (4), (b) (6) System	18 Sep 2020 17:02:30
	System	18 Sep 2020 17:02:30



US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:01:40', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '56d2e074-2b70-4135-a489-10e32982e2ed'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	18 Sep 2020 17:02:30

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
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 'IBUPROFEN WAS TAKEN' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:11:42
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)	01 Oct 2020 16:18:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:01:44', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '56d2e074-2b70-4135-a489-10e32982e2ed'	System	18 Sep 2020 17:02:30
User entered '1'	System	18 Sep 2020 17:02:30

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:01:44', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '56d2e074-2b70-4135-a489-10e32982e2ed' User entered '0'	(b) (4), (b) (6) System	18 Sep 2020 17:02:30
	System	18 Sep 2020 17:02:30

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:01:49', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '56d2e074-2b70-4135-a489-10e32982e2ed'	(b) (4), (b) (6) System	18 Sep 2020 17:02:30
User entered '18 Sep 2020 12:01'	System	18 Sep 2020 17:02:30

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 3'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:04:57', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c2cb3ef9-0fc2-4939-b3bd-94c4a2283745'	(b) (4), (b) (6)	
	System	19 Sep 2020 17:05:08
User entered 'Yes (Y)'	System	19 Sep 2020 17:05:08



US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c2cb3ef9-0fc2-4939-b3bd-94c4a2283745'	(b) (4), (b) (6)	
User entered '98.7'	System	19 Sep 2020 17:05:08

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:04', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c2cb3ef9-0fc2-4939-b3bd-94c4a2283745'	(b) (4), (b) (6) System	19 Sep 2020 17:05:08
User entered 'No (N)'	System	19 Sep 2020 17:05:08

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:06', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c2cb3ef9-0fc2-4939-b3bd-94c4a2283745'	(b) (4), (b) (6) System	19 Sep 2020 17:05:08
User entered '19 Sep 2020 12:05'	System	19 Sep 2020 17:05:08

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 4'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:00:52', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '4529a62f-9bb3-48ad-9011-7f86fb82a1e2'	(b) (4), (b) (6) System	20 Sep 2020 17:01:24
User entered 'Yes (Y)'	System	20 Sep 2020 17:01:24

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:00:57', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '4529a62f-9bb3-48ad-9011-7f86fb82a1e2'	(b) (4), (b) (6)	
User entered '93.7'	System	20 Sep 2020 17:01:24



US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:01:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '4529a62f-9bb3-48ad-9011-7f86fb82a1e2'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:01:24
User entered 'No (N)'	System	20 Sep 2020 17:01:24

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:01:14', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '4529a62f-9bb3-48ad-9011-7f86fb82a1e2'	(b) (4), (b) (6) System	20 Sep 2020 17:01:24
User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:01:24

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 5'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:28', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '507afe46-9d66-40fd-934d-1aa7519ae9cf'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	21 Sep 2020 17:03:15

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:34', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '507afe46-9d66-40fd-934d-1aa7519ae9cf'	(b) (4), (b) (6)	
User entered '99.1'	System	21 Sep 2020 17:03:15

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:36', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '507afe46-9d66-40fd-934d-1aa7519ae9cf'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Sep 2020 17:03:15



US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:38', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '507afe46-9d66-40fd-934d-1aa7519ae9cf'	(b) (4), (b) (6) System	21 Sep 2020 17:03:15
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:03:15

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 6'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:00:57', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e09a5ecd-ee72-4278-91d9-a2b0c368d96d'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	22 Sep 2020 17:01:53

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e09a5ecd-ee72-4278-91d9-a2b0c368d96d' User entered '98.5'	(b) (4), (b) (6) System	22 Sep 2020 17:01:53
	System	22 Sep 2020 17:01:53

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:02', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e09a5ecd-ee72-4278-91d9-a2b0c368d96d'	(b) (4), (b) (6)	
User entered 'No (N)'	System	22 Sep 2020 17:01:53

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:04', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e09a5ecd-ee72-4278-91d9-a2b0c368d96d'	(b) (4), (b) (6) System	22 Sep 2020 17:01:53
User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:01:53



US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 7'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:00:55', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8a4e08c2-4f52-4392-86b5-f6158394589a'	(b) (4), (b) (6) System	23 Sep 2020 17:03:30
User entered 'Yes (Y)'	System	23 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:00:58', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8a4e08c2-4f52-4392-86b5-f6158394589a' User entered '97.8'	(b) (4), (b) (6) System	23 Sep 2020 17:03:30
	System	23 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:03', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8a4e08c2-4f52-4392-86b5-f6158394589a'	(b) (4), (b) (6)	
	System	23 Sep 2020 17:03:30
User entered 'No (N)'	System	23 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:04', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8a4e08c2-4f52-4392-86b5-f6158394589a'	(b) (4), (b) (6) System	23 Sep 2020 17:03:30
User entered '23 Sep 2020 12:01'	System	23 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '24 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:45:39', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2d881e76-add2-41c1-9885-34fef3c26eb5'	(b) (4), (b) (6) System	17 Sep 2020 21:46:05
User entered 'None (1)'	System	17 Sep 2020 21:46:05

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:45:56', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2d881e76-add2-41c1-9885-34fef3c26eb5'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Sep 2020 21:46:05

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:45:58', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2d881e76-add2-41c1-9885-34fef3c26eb5'	(b) (4), (b) (6) System	17 Sep 2020 21:46:05
User entered 'No (N)'	System	17 Sep 2020 21:46:05

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:45:59', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2d881e76-add2-41c1-9885-34fef3c26eb5'	(b) (4), (b) (6) System	17 Sep 2020 21:46:05
User entered 'None (1)'	System	17 Sep 2020 21:46:05

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:46:02', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2d881e76-add2-41c1-9885-34fef3c26eb5'	(b) (4), (b) (6) System	17 Sep 2020 21:46:05
User entered '17 Sep 2020 16:46'	System	17 Sep 2020 21:46:05

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '17 Sep 2020 16:28'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '17 Sep 2020 18:58'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:53:52', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5459ed99-4e74-42d4-bffb-cae0fb261afa'	(b) (4), (b) (6) System	18 Sep 2020 00:54:44
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 00:54:44

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:54:08', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5459ed99-4e74-42d4-bffb-cae0fb261afa'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Sep 2020 00:54:44

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:54:10', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5459ed99-4e74-42d4-bffb-cae0fb261afa'	(b) (4), (b) (6) System	18 Sep 2020 00:54:44
User entered 'No (N)'	System	18 Sep 2020 00:54:44

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:54:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5459ed99-4e74-42d4-bffb-cae0fb261afa'	(b) (4), (b) (6) System	18 Sep 2020 00:54:44
User entered 'None (1)'	System	18 Sep 2020 00:54:44

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:54:41', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5459ed99-4e74-42d4-bffb-cae0fb261afa'	(b) (4), (b) (6) System	18 Sep 2020 00:54:44
User entered '17 Sep 2020 19:54'	System	18 Sep 2020 00:54:44

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '17 Sep 2020 19:53'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 2'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:10', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '85dcd2c6-b284-4b1d-9d0e-48709a600310'	(b) (4), (b) (6) System	18 Sep 2020 17:04:16
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 17:04:16

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:03:38', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '85dcd2c6-b284-4b1d-9d0e-48709a600310'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Sep 2020 17:04:16

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:03:43', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '85dcd2c6-b284-4b1d-9d0e-48709a600310'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Sep 2020 17:04:16

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:03:49', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '85dcd2c6-b284-4b1d-9d0e-48709a600310'	(b) (4), (b) (6) System	18 Sep 2020 17:04:16
User entered 'None (1)'	System	18 Sep 2020 17:04:16

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:13', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '85dcd2c6-b284-4b1d-9d0e-48709a600310'	(b) (4), (b) (6) System	18 Sep 2020 17:04:16
User entered '18 Sep 2020 12:04'	System	18 Sep 2020 17:04:16

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 3'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:10', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '752424ef-ee4e-4cc1-9a2c-ce60103e4950'	(b) (4), (b) (6) System	19 Sep 2020 17:05:24
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 17:05:24

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:12', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '752424ef-ee4e-4cc1-9a2c-ce60103e4950'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Sep 2020 17:05:24

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:16', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '752424ef-ee4e-4cc1-9a2c-ce60103e4950'	(b) (4), (b) (6) System	19 Sep 2020 17:05:24
User entered 'No (N)'	System	19 Sep 2020 17:05:24

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:19', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '752424ef-ee4e-4cc1-9a2c-ce60103e4950'	(b) (4), (b) (6) System	19 Sep 2020 17:05:24
User entered 'None (1)'	System	19 Sep 2020 17:05:24

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:21', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '752424ef-ee4e-4cc1-9a2c-ce60103e4950'	(b) (4), (b) (6) System	19 Sep 2020 17:05:24
User entered '19 Sep 2020 12:05'	System	19 Sep 2020 17:05:24

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 4'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:01:17', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '655107b6-ab10-4345-8419-78e0b034acd4'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:02:12
User entered 'None (1)'	System	20 Sep 2020 17:02:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:01:19', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '655107b6-ab10-4345-8419-78e0b034acd4'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Sep 2020 17:02:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:01:21', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '655107b6-ab10-4345-8419-78e0b034acd4'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Sep 2020 17:02:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:01:22', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '655107b6-ab10-4345-8419-78e0b034acd4'	(b) (4), (b) (6) System	20 Sep 2020 17:02:12
User entered 'None (1)'	System	20 Sep 2020 17:02:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:01:53', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '655107b6-ab10-4345-8419-78e0b034acd4'	(b) (4), (b) (6) System	20 Sep 2020 17:02:12
User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:02:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 5'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:42', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '54a25c5b-54ac-4c11-b593-bacdbe24df94'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:03:29
User entered 'None (1)'	System	21 Sep 2020 17:03:29

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:44', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '54a25c5b-54ac-4c11-b593-bacdbe24df94'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Sep 2020 17:03:29

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:45', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '54a25c5b-54ac-4c11-b593-bacdbe24df94'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:03:29
User entered 'No (N)'	System	21 Sep 2020 17:03:29

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:47', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '54a25c5b-54ac-4c11-b593-bacdbe24df94'	(b) (4), (b) (6) System	21 Sep 2020 17:03:29
User entered 'None (1)'	System	21 Sep 2020 17:03:29

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:49', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '54a25c5b-54ac-4c11-b593-bacdbe24df94'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:03:29
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:03:29

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 6'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '72d03ddb-a762-43e8-b32e-ebf13487b2b8'	(b) (4), (b) (6) System	22 Sep 2020 17:02:10
User entered 'None (1)'	System	22 Sep 2020 17:02:10

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:08', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '72d03ddb-a762-43e8-b32e-ebf13487b2b8'	(b) (4), (b) (6)	
User entered 'No (N)'	System	22 Sep 2020 17:02:10

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:09', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '72d03ddb-a762-43e8-b32e-ebf13487b2b8'	(b) (4), (b) (6)	
User entered 'No (N)'	System	22 Sep 2020 17:02:10

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:11', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '72d03ddb-a762-43e8-b32e-ebf13487b2b8'	(b) (4), (b) (6) System	22 Sep 2020 17:02:10
User entered 'None (1)'	System	22 Sep 2020 17:02:10

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:13', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '72d03ddb-a762-43e8-b32e-ebf13487b2b8'	(b) (4), (b) (6) System	22 Sep 2020 17:02:10
User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:02:10

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 7'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5eb853fb-e435-4e0a-aea3-177caf4370a4'	(b) (4), (b) (6)	
	System	23 Sep 2020 17:04:12
User entered 'None (1)'	System	23 Sep 2020 17:04:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:08', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5eb853fb-e435-4e0a-aea3-177caf4370a4'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Sep 2020 17:04:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:10', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5eb853fb-e435-4e0a-aea3-177caf4370a4'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Sep 2020 17:04:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:11', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5eb853fb-e435-4e0a-aea3-177caf4370a4'	(b) (4), (b) (6)	23 Sep 2020 17:04:12
User entered 'None (1)'	System	23 Sep 2020 17:04:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:13', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '5eb853fb-e435-4e0a-aea3-177caf4370a4'	(b) (4), (b) (6) System	23 Sep 2020 17:04:12
User entered '23 Sep 2020 12:01'	System	23 Sep 2020 17:04:12

US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '24 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:46:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'df06c672-778f-453a-b7b8-f741035baeb3'	(b) (4), (b) (6)	
User entered 'None (0)'	System	17 Sep 2020 21:46:17

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:46:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'df06c672-778f-453a-b7b8-f741035baeb3'	(b) (4), (b) (6) System	17 Sep 2020 21:46:17
User entered 'None (0)'	System	17 Sep 2020 21:46:17

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:46:08', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'df06c672-778f-453a-b7b8-f741035baeb3'	(b) (4), (b) (6) System	17 Sep 2020 21:46:17
User entered 'None (0)'	System	17 Sep 2020 21:46:17

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:46:09', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'df06c672-778f-453a-b7b8-f741035baeb3'	(b) (4), (b) (6) System	17 Sep 2020 21:46:17
User entered 'None (0)'	System	17 Sep 2020 21:46:17

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:46:10', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'df06c672-778f-453a-b7b8-f741035baeb3'	(b) (4), (b) (6)	
User entered 'None (0)'	System	17 Sep 2020 21:46:17

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:46:11', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'df06c672-778f-453a-b7b8-f741035baeb3'	(b) (4), (b) (6)	
User entered 'None (0)'	System	17 Sep 2020 21:46:17



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:46:13', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'df06c672-778f-453a-b7b8-f741035baeb3'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Sep 2020 21:46:17

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T16:46:15', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'df06c672-778f-453a-b7b8-f741035baeb3'	(b) (4), (b) (6) System	17 Sep 2020 21:46:17
User entered '17 Sep 2020 16:46'	System	17 Sep 2020 21:46:17

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '17 Sep 2020 16:28'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '17 Sep 2020 18:58'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:55:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6803821a-1279-45f4-a140-7c47e0e7f239'	(b) (4), (b) (6)	
	System	18 Sep 2020 00:55:21
User entered 'None (0)'	System	18 Sep 2020 00:55:21

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:55:03', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6803821a-1279-45f4-a140-7c47e0e7f239'	(b) (4), (b) (6) System	18 Sep 2020 00:55:21
User entered 'None (0)'	System	18 Sep 2020 00:55:21

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:55:06', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6803821a-1279-45f4-a140-7c47e0e7f239'	(b) (4), (b) (6) System	18 Sep 2020 00:55:21
User entered 'None (0)'	System	18 Sep 2020 00:55:21



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:55:09', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6803821a-1279-45f4-a140-7c47e0e7f239'	(b) (4), (b) (6) System	18 Sep 2020 00:55:21
User entered 'None (0)'	System	18 Sep 2020 00:55:21

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:55:11', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6803821a-1279-45f4-a140-7c47e0e7f239'	(b) (4), (b) (6) System	18 Sep 2020 00:55:21
User entered 'None (0)'	System	18 Sep 2020 00:55:21

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:55:14', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6803821a-1279-45f4-a140-7c47e0e7f239'	(b) (4), (b) (6)	18 Sep 2020 00:55:21
User entered 'None (0)'	System	18 Sep 2020 00:55:21

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:55:16', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6803821a-1279-45f4-a140-7c47e0e7f239'	(b) (4), (b) (6)	18 Sep 2020 00:55:21
User entered 'No (N)'	System	18 Sep 2020 00:55:21

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-17T19:55:18', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6803821a-1279-45f4-a140-7c47e0e7f239'	(b) (4), (b) (6) System	18 Sep 2020 00:55:21
User entered '17 Sep 2020 19:55'	System	18 Sep 2020 00:55:21

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '17 Sep 2020 19:53'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 2'	System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:18', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c54c52ed-9b6c-4545-8443-f76ecccdfa76'	(b) (4), (b) (6)	
User entered 'None (0)'	System	18 Sep 2020 17:04:34

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:20', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c54c52ed-9b6c-4545-8443-f76ecccdfa76'	(b) (4), (b) (6) System	18 Sep 2020 17:04:34
User entered 'None (0)'	System	18 Sep 2020 17:04:34

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:22', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c54c52ed-9b6c-4545-8443-f76ecccdfa76'	(b) (4), (b) (6)	
User entered 'None (0)'	System	18 Sep 2020 17:04:34

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:23', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c54c52ed-9b6c-4545-8443-f76ecccdfa76'	(b) (4), (b) (6)	18 Sep 2020 17:04:34
User entered 'None (0)'	System	18 Sep 2020 17:04:34

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:25', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c54c52ed-9b6c-4545-8443-f76ecccdfa76'	(b) (4), (b) (6)	
User entered 'None (0)'	System	18 Sep 2020 17:04:34

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c54c52ed-9b6c-4545-8443-f76ecccdfa76'	(b) (4), (b) (6) System	18 Sep 2020 17:04:34
User entered 'None (0)'	System	18 Sep 2020 17:04:34

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:28', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c54c52ed-9b6c-4545-8443-f76ecccdfa76'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Sep 2020 17:04:34

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-18T12:04:31', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c54c52ed-9b6c-4545-8443-f76eccdfa76'	(b) (4), (b) (6) System	18 Sep 2020 17:04:34
User entered '18 Sep 2020 12:04'	System	18 Sep 2020 17:04:34



**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 3'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:24', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3453da-8526-41f5-8362-99cd33927024'	(b) (4), (b) (6)	
User entered 'None (0)'	System	19 Sep 2020 17:05:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3453da-8526-41f5-8362-99cd33927024'	(b) (4), (b) (6) System	19 Sep 2020 17:05:40
User entered 'None (0)'	System	19 Sep 2020 17:05:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:27', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3453da-8526-41f5-8362-99cd33927024'	(b) (4), (b) (6) System	19 Sep 2020 17:05:40
User entered 'None (0)'	System	19 Sep 2020 17:05:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:29', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3453da-8526-41f5-8362-99cd33927024'	(b) (4), (b) (6) System	19 Sep 2020 17:05:40
User entered 'None (0)'	System	19 Sep 2020 17:05:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:31', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3453da-8526-41f5-8362-99cd33927024'	(b) (4), (b) (6) System	19 Sep 2020 17:05:40
User entered 'None (0)'	System	19 Sep 2020 17:05:40



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:33', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3453da-8526-41f5-8362-99cd33927024'	(b) (4), (b) (6) System	19 Sep 2020 17:05:40
User entered 'None (0)'	System	19 Sep 2020 17:05:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:35', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3453da-8526-41f5-8362-99cd33927024'	(b) (4), (b) (6) System	19 Sep 2020 17:05:40
User entered 'No (N)'	System	19 Sep 2020 17:05:40

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-19T12:05:37', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3453da-8526-41f5-8362-99cd33927024'	(b) (4), (b) (6) System	19 Sep 2020 17:05:40
User entered '19 Sep 2020 12:05'	System	19 Sep 2020 17:05:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 4'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:02:27', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'aa9f1c46-11c1-40b2-bcbc-ee4ee41cb611'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:02:31', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'aa9f1c46-11c1-40b2-bcbc-ee4ee41cb611'	(b) (4), (b) (6) System	20 Sep 2020 17:03:30
User entered 'None (0)'	System	20 Sep 2020 17:03:30



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:02:36', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'aa9f1c46-11c1-40b2-bcbc-ee4ee41cb611'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:02:43', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'aa9f1c46-11c1-40b2-bcbc-ee4ee41cb611'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:02:48', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'aa9f1c46-11c1-40b2-bcbc-ee4ee41cb611'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:03:30
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:02:52', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'aa9f1c46-11c1-40b2-bcbc-ee4ee41cb611'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:03:30
User entered 'None (0)'	System	20 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:02:55', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'aa9f1c46-11c1-40b2-bcbc-ee4ee41cb611'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:03:30
User entered 'No (N)'	System	20 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-20T12:02:57', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'aa9f1c46-11c1-40b2-bcbc-ee4ee41cb611'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:03:30
User entered '20 Sep 2020 12:02'	System	20 Sep 2020 17:03:30

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:55:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 5'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:00:59', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'b2a8a470-53da-4a73-b92d-f02c23eaa2e9'	(b) (4), (b) (6) System	21 Sep 2020 17:04:32
User entered 'No interference with activity (1)'	System	21 Sep 2020 17:04:32

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:01:03', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'b2a8a470-53da-4a73-b92d-f02c23eaa2e9'	(b) (4), (b) (6) System	21 Sep 2020 17:04:32
User entered 'Some interference with activity (2)'	System	21 Sep 2020 17:04:32

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:01:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'b2a8a470-53da-4a73-b92d-f02c23eaa2e9'	(b) (4), (b) (6) System	21 Sep 2020 17:04:32
User entered 'No interference with activity (1)'	System	21 Sep 2020 17:04:32

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:01:09', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'b2a8a470-53da-4a73-b92d-f02c23eaa2e9'	(b) (4), (b) (6) System	21 Sep 2020 17:04:32
User entered 'None (0)'	System	21 Sep 2020 17:04:32

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:01:17', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'b2a8a470-53da-4a73-b92d-f02c23eaa2e9'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:04:32
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	21 Sep 2020 17:04:32

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:01:20', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'b2a8a470-53da-4a73-b92d-f02c23eaa2e9'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:04:32
User entered 'No interference with activity (1)'	System	21 Sep 2020 17:04:32

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:01:22', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'b2a8a470-53da-4a73-b92d-f02c23eaa2e9'	(b) (4), (b) (6) System	21 Sep 2020 17:04:32
User entered 'No (N)'	System	21 Sep 2020 17:04:32



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-21T12:01:24', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'b2a8a470-53da-4a73-b92d-f02c23eaa2e9'	(b) (4), (b) (6) System	21 Sep 2020 17:04:32
User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:04:32

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '21 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 6'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:17', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '878dc45d-ee9f-4a9c-abc3-197673a0fa90'	(b) (4), (b) (6) System	22 Sep 2020 17:03:20
User entered 'No interference with activity (1)'	System	22 Sep 2020 17:03:20

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:19', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '878dc45d-ee9f-4a9c-abc3-197673a0fa90'	(b) (4), (b) (6) System	22 Sep 2020 17:03:20
User entered 'No interference with activity (1)'	System	22 Sep 2020 17:03:20

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:21', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '878dc45d-ee9f-4a9c-abc3-197673a0fa90'	(b) (4), (b) (6)	
User entered 'None (0)'	System	22 Sep 2020 17:03:20

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:23', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '878dc45d-ee9f-4a9c-abc3-197673a0fa90'	(b) (4), (b) (6)	
User entered 'None (0)'	System	22 Sep 2020 17:03:20



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:33', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '878dc45d-ee9f-4a9c-abc3-197673a0fa90'	(b) (4), (b) (6)	
	System	22 Sep 2020 17:03:20
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Sep 2020 17:03:20

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:36', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '878dc45d-ee9f-4a9c-abc3-197673a0fa90'	(b) (4), (b) (6) System	22 Sep 2020 17:03:20
User entered 'None (0)'	System	22 Sep 2020 17:03:20

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:38', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '878dc45d-ee9f-4a9c-abc3-197673a0fa90'	(b) (4), (b) (6)	
User entered 'No (N)'	System	22 Sep 2020 17:03:20

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:55:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-22T12:01:40', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '878dc45d-ee9f-4a9c-abc3-197673a0fa90'	(b) (4), (b) (6) System	22 Sep 2020 17:03:20
User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:03:20

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 21:28:40
User entered 'Day 7'	System	17 Sep 2020 21:28:40

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:16', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e9273220-8890-44fb-90e5-b020609105bd'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:04:44



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:17', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e9273220-8890-44fb-90e5-b020609105bd'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:04:44

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:18', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e9273220-8890-44fb-90e5-b020609105bd'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:04:44

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:20', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e9273220-8890-44fb-90e5-b020609105bd'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:04:44

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:22', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e9273220-8890-44fb-90e5-b020609105bd'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:04:44

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:23', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e9273220-8890-44fb-90e5-b020609105bd'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:04:44

US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:25', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e9273220-8890-44fb-90e5-b020609105bd'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Sep 2020 17:04:44

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-09-23T12:01:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'e9273220-8890-44fb-90e5-b020609105bd' User entered '23 Sep 2020 12:01'	(b) (4), (b) (6) System	23 Sep 2020 17:04:44
	System	23 Sep 2020 17:04:44

**US3042262**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:55:45**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '23 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40



US3042262

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:55:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
User entered '24 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 21:28:40

**US3042262**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:27
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:01

**US3042262**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:27
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered '24 Sep 2020'	Rylea Gulick (b) (4)	24 Sep 2020 21:03:01

**US3042262**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:27
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4)	24 Sep 2020 21:03:01

US3042262

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:27
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 21:03:01

US3042262

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:27
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:03

US3042262

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:27
User entered 'I'	System	24 Sep 2020 21:03:03

**US3042262**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:30
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 16:16:48



**US3042262**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:30
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered '01 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 16:16:48

**US3042262**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:30
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	01 Oct 2020 16:16:48

US3042262

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:30
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	Rylea Gulick (b) (4)	01 Oct 2020 16:16:48

US3042262

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:30
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 16:16:49

**US3042262**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:30
User entered 'I'	System	01 Oct 2020 16:16:49

US3042262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:15
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	16 Oct 2020 21:53:22
	(b) (4)	

US3042262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:15
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Oct 2020 21:53:22
	(b) (4)	

US3042262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:15
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Oct 2020 21:53:22
	(b) (4)	



US3042262

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:15
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Oct 2020 21:53:22
	(b) (4)	

US3042262

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:15
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Oct 2020 21:53:24
	(b) (4)	

**US3042262**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:15
User entered 'I'	System	16 Oct 2020 21:53:24

US3042262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 21:53:30

US3042262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16 Oct 2020'	Rylea Gulick (b) (4)	16 Oct 2020 21:53:30
	(b) (4)	

US3042262

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[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 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	16 Oct 2020 21:53:30
	(b) (4)	

**US3042262**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User entered 'VISIT3'	(b) (4), (b) (6) System	16 Oct 2020 21:53:30

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 21:53:52



US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '16 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 21:53:52

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16:10'	Rylea Gulick (b) (4)	16 Oct 2020 21:53:52
	(b) (4)	

**US3042262**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User entered '16 Oct 2020 16:10'	(b) (4), (b) (6) System	16 Oct 2020 21:53:52

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '36.5' C	Rylea Gulick (b) (4)	16 Oct 2020 21:53:52
	(b) (4)	

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	16 Oct 2020 21:53:52
	(b) (4)	

**US3042262**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Oct 2020 21:53:52
	(b) (4)	

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Oct 2020 21:54:03
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Oct 2020 21:54:03
User entered '89' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Oct 2020 21:54:03
	(b) (4)	
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Oct 2020 21:53:52
User entered '891'	Rylea Gulick (b) (4)	16 Oct 2020 21:53:52
	(b) (4)	

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User entered 'bpm'	(b) (4), (b) (6) System	16 Oct 2020 21:53:52



US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 21:54:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Oct 2020 21:54:03
User entered '12' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Oct 2020 21:54:03
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 21:53:52
User entered empty.	Rylea Gulick (b) (4)	16 Oct 2020 21:53:52
	(b) (4)	

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	16 Oct 2020 21:54:03
User entered empty.	System	16 Oct 2020 21:53:52

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 21:54:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Oct 2020 21:54:03
User entered '133' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Oct 2020 21:54:03
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 21:53:52
User entered empty.	Rylea Gulick (b) (4)	16 Oct 2020 21:53:52
	(b) (4)	

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User entered 'mmHg'	(b) (4), (b) (6)	
	System	16 Oct 2020 21:54:03
User entered empty.	System	16 Oct 2020 21:53:52

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 21:54:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Oct 2020 21:54:03
User entered '86' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Oct 2020 21:54:03
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 21:53:52
User entered empty.	Rylea Gulick (b) (4)	16 Oct 2020 21:53:52
	(b) (4)	

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User entered 'mmHg'	System	16 Oct 2020 21:54:03
User entered empty.	System	16 Oct 2020 21:53:52

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:21

US3042262

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:21



US3042262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 21:54:17

US3042262

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16 Oct 2020'	Rylea Gulick (b) (4)	16 Oct 2020 21:54:17
	(b) (4)	

US3042262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 21:54:24

US3042262

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '16 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 21:54:24

**US3042262**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:45**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16:12'	Rylea Gulick (b) (4)	16 Oct 2020 21:54:24
	(b) (4)	

**US3042262**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User entered '16 Oct 2020 16:12'	(b) (4), (b) (6) System	16 Oct 2020 21:54:24

US3042262

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Oct 2020 21:54:26
	(b) (4)	

**US3042262**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:21
User entered '1'	(b) (4), (b) (6) System	16 Oct 2020 21:54:26



US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 64'	System	20 Aug 2020 20:33:51

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-10-23T10:47:27', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '568e314c-799f-48ae-aad3-dfd0d8e3d30e'	(b) (4), (b) (6)	23 Oct 2020 15:47:37
User entered 'No (N)'	System	23 Oct 2020 15:47:37

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

Have you been exposed to someone with 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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-10-23T10:47:29', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '568e314c-799f-48ae-aad3-dfd0d8e3d30e'	(b) (4), (b) (6)	23 Oct 2020 15:47:37
User entered 'No (N)'	System	23 Oct 2020 15:47:37

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-10-23T10:47:33', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '568e314c-799f-48ae-aad3-dfd0d8e3d30e' User entered '23 Oct 2020 10:47:33'	(b) (4), (b) (6) System	23 Oct 2020 15:47:37
	System	23 Oct 2020 15:47:37

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 20:33:51

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 20:33:51

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 71'	System	20 Aug 2020 20:33:51

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

[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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-10-27T08:04:55', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'dc4b31a1-c49f-4340-b970-8e1163ad8ac8'	(b) (4), (b) (6)	27 Oct 2020 13:05:11
User entered 'No (N)'	System	27 Oct 2020 13:05:11



US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

Have you been exposed to someone with 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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-10-27T08:05:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'dc4b31a1-c49f-4340-b970-8e1163ad8ac8'	(b) (4), (b) (6)	27 Oct 2020 13:05:11
User entered 'No (N)'	System	27 Oct 2020 13:05:11

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-10-27T08:05:07', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'dc4b31a1-c49f-4340-b970-8e1163ad8ac8'	(b) (4), (b) (6) System	27 Oct 2020 13:05:11
User entered '27 Oct 2020 08:05:07'	System	27 Oct 2020 13:05:11

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 20:33:51

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 20:33:51

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 78'	System	20 Aug 2020 20:33:51

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-11-03T06:55:14', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21c3dc2c-2867-4a2f-8e2e-5d8954e990fd'	(b) (4), (b) (6)	
	System	03 Nov 2020 12:55:20
User entered 'No (N)'	System	03 Nov 2020 12:55:20

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

Have you been exposed to someone with 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 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-11-03T06:55:13', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21c3dc2c-2867-4a2f-8e2e-5d8954e990fd'	(b) (4), (b) (6)	
	System	03 Nov 2020 12:55:20
User entered 'No (N)'	System	03 Nov 2020 12:55:20

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-11-03T06:55:19', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '21c3dc2c-2867-4a2f-8e2e-5d8954e990fd'	(b) (4), (b) (6) System	03 Nov 2020 12:55:20
User entered '03 Nov 2020 06:55:19'	System	03 Nov 2020 12:55:20



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 20:33:51

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:41
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 20:33:51
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 20:33:51

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01
Data entry locked.	System	20 Aug 2020 20:33:51
User entered 'Day 92'	System	20 Aug 2020 20:33:51

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

[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 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

[Have you been exposed to someone with 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 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

US3042262

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:55:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01
Data entry locked.	System	20 Aug 2020 20:33:51
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 20:33:51

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:01
Data entry locked.	System	20 Aug 2020 20:33:51
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 20:33:51

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:11:01

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:11:01



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2020-12-07T17:44:42', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '057bd6b7-0300-47e6-8a82-c9aa3cb61894'	System	07 Dec 2020 23:44:54
User entered 'No (N)'	System	07 Dec 2020 23:44:54

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2020-12-07T17:44:49', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '057bd6b7-0300-47e6-8a82-c9aa3cb61894'	System	07 Dec 2020 23:44:54
User entered 'No (N)'	System	07 Dec 2020 23:44:54

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-12-07T17:44:52', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '057bd6b7-0300-47e6-8a82-c9aa3cb61894'	System	07 Dec 2020 23:44:54
User entered '07 Dec 2020 17:44:52'	System	07 Dec 2020 23:44:54



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2020-12-12T08:07:50', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '95655c51-fc0a-4af0-b58c-e7eb7dbc1804'	System	12 Dec 2020 14:08:00
User entered 'No (N)'	System	12 Dec 2020 14:08:00

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2020-12-12T08:07:54', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '95655c51-fc0a-4af0-b58c-e7eb7dbc1804'	System	12 Dec 2020 14:08:00
User entered 'No (N)'	System	12 Dec 2020 14:08:00

**US3042262**

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

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**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-12-12T08:07:57', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '95655c51-fc0a-4af0-b58c-e7eb7dbc1804'	System	12 Dec 2020 14:08:00
User entered '12 Dec 2020 08:07:57'	System	12 Dec 2020 14:08:00

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:11:01

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:11:01



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:11:01

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2020-12-19T06:33:02', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'a29f3435-cf3d-42f1-b9dd-ac0bab63646c'	System	19 Dec 2020 12:33:17
User entered 'No (N)'	System	19 Dec 2020 12:33:17

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2020-12-19T06:33:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'a29f3435-cf3d-42f1-b9dd-ac0bab63646c'	System	19 Dec 2020 12:33:17
User entered 'No (N)'	System	19 Dec 2020 12:33:17

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-12-19T06:33:08', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'a29f3435-cf3d-42f1-b9dd-ac0bab63646c'	System	19 Dec 2020 12:33:17
User entered '19 Dec 2020 06:33:08'	System	19 Dec 2020 12:33:17

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:11:01

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

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2020-12-28T07:07:38', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c32e72a1-9039-4a50-84a4-82adf035488f'	System	28 Dec 2020 13:08:04
User entered 'No (N)'	System	28 Dec 2020 13:08:04



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2020-12-28T07:07:54', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c32e72a1-9039-4a50-84a4-82adf035488f'	System	28 Dec 2020 13:08:04
User entered 'No (N)'	System	28 Dec 2020 13:08:04

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2020-12-28T07:08:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c32e72a1-9039-4a50-84a4-82adf035488f' User entered '28 Dec 2020 07:08:00'	System	28 Dec 2020 13:08:04
	System	28 Dec 2020 13:08:04

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:11:01

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:11:01

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-01-04T09:00:08', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '002e25d5-cd0f-4441-812f-d6d7bf5305c7'	System	04 Jan 2021 15:00:17
User entered 'No (N)'	System	04 Jan 2021 15:00:17

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-01-04T09:00:11', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '002e25d5-cd0f-4441-812f-d6d7bf5305c7'	System	04 Jan 2021 15:00:17
User entered 'No (N)'	System	04 Jan 2021 15:00:17

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-01-04T09:00:14', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '002e25d5-cd0f-4441-812f-d6d7bf5305c7'	System	04 Jan 2021 15:00:17
User entered '04 Jan 2021 09:00:14'	System	04 Jan 2021 15:00:17



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-01-11T18:30:35', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '43ee85ca-036a-4a9d-969b-ccc2bd04cff4'	System	12 Jan 2021 00:30:46
User entered 'No (N)'	System	12 Jan 2021 00:30:46

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-01-11T18:30:36', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '43ee85ca-036a-4a9d-969b-ccc2bd04cff4'	System	12 Jan 2021 00:30:46
User entered 'No (N)'	System	12 Jan 2021 00:30:46

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-01-11T18:30:42', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '43ee85ca-036a-4a9d-969b-ccc2bd04cff4'	System	12 Jan 2021 00:30:46
User entered '11 Jan 2021 18:30:42'	System	12 Jan 2021 00:30:46

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-01-16T00:20:17', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c1f84f0c-a5b5-46e1-87fe-69ff50bade85'	System	16 Jan 2021 06:20:24
User entered 'No (N)'	System	16 Jan 2021 06:20:24

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-01-16T00:20:19', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c1f84f0c-a5b5-46e1-87fe-69ff50bade85'	System	16 Jan 2021 06:20:24
User entered 'No (N)'	System	16 Jan 2021 06:20:24

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-01-16T00:20:21', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c1f84f0c-a5b5-46e1-87fe-69ff50bade85'	System	16 Jan 2021 06:20:24
User entered '16 Jan 2021 00:20:21'	System	16 Jan 2021 06:20:24

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-01-25T18:31:05', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8badcb0b-fa73-4e4f-b267-c023e3880bee'	System	26 Jan 2021 00:31:10
User entered 'No (N)'	System	26 Jan 2021 00:31:10



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-01-25T18:31:06', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8badcb0b-fa73-4e4f-b267-c023e3880bee'	System	26 Jan 2021 00:31:10
User entered 'No (N)'	System	26 Jan 2021 00:31:10

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-01-25T18:31:09', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8badcb0b-fa73-4e4f-b267-c023e3880bee'	System	26 Jan 2021 00:31:10
User entered '25 Jan 2021 18:31:09'	System	26 Jan 2021 00:31:10

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-01-30T06:45:44', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '3f1bd673-f822-461b-b4bc-44cdf009f28a'	System	30 Jan 2021 12:45:55
User entered 'No (N)'	System	30 Jan 2021 12:45:55

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-01-30T06:45:47', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '3f1bd673-f822-461b-b4bc-44cdf009f28a'	System	30 Jan 2021 12:45:55
User entered 'No (N)'	System	30 Jan 2021 12:45:55

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-01-30T06:45:51', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '3f1bd673-f822-461b-b4bc-44cdf009f28a'	System	30 Jan 2021 12:45:55
User entered '30 Jan 2021 06:45:51'	System	30 Jan 2021 12:45:55



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-02-08T18:34:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c3be9add-6341-47b8-ac64-d158c2e363ed'	System	09 Feb 2021 00:34:08
User entered 'No (N)'	System	09 Feb 2021 00:34:08

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-02-08T18:34:03', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c3be9add-6341-47b8-ac64-d158c2e363ed'	System	09 Feb 2021 00:34:08
User entered 'No (N)'	System	09 Feb 2021 00:34:08

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-02-08T18:34:06', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'c3be9add-6341-47b8-ac64-d158c2e363ed'	System	09 Feb 2021 00:34:08
User entered '08 Feb 2021 18:34:06'	System	09 Feb 2021 00:34:08

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-02-22T13:54:23', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6ef3d0c1-cbf3-4adc-9160-80401e682156'	System	22 Feb 2021 19:54:32
User entered 'No (N)'	System	22 Feb 2021 19:54:32

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-02-22T13:54:24', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6ef3d0c1-cbf3-4adc-9160-80401e682156'	System	22 Feb 2021 19:54:32
User entered 'No (N)'	System	22 Feb 2021 19:54:32

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-02-22T13:54:26', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '6ef3d0c1-cbf3-4adc-9160-80401e682156'	System	22 Feb 2021 19:54:32
User entered '22 Feb 2021 13:54:26'	System	22 Feb 2021 19:54:32

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-02-27T06:45:57-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '1f154e13-3484-445f-94e6-ed0679b4baf5'	System	27 Feb 2021 12:46:06
User entered 'No (N)'	System	27 Feb 2021 12:46:06

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-02-27T06:45:59-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '1f154e13-3484-445f-94e6-ed0679b4baf5'	System	27 Feb 2021 12:46:06
User entered 'No (N)'	System	27 Feb 2021 12:46:06

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-02-27T06:46:03-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '1f154e13-3484-445f-94e6-ed0679b4baf5' User entered '27 Feb 2021 06:46:03'	System	27 Feb 2021 12:46:06
	System	27 Feb 2021 12:46:06

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-03-06T06:46:38-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '43a79935-3621-4467-94b9-c4da61aa806e'	System	06 Mar 2021 12:47:13
User entered 'Yes (Y)'	System	06 Mar 2021 12:47:13

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-03-06T06:46:34-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '43a79935-3621-4467-94b9-c4da61aa806e'	System	06 Mar 2021 12:47:13
User entered 'No (N)'	System	06 Mar 2021 12:47:13

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-03-06T06:46:34-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '43a79935-3621-4467-94b9-c4da61aa806e'	System	06 Mar 2021 12:47:13
User entered 'No (N)'	System	06 Mar 2021 12:47:13

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-03-06T06:46:44-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '43a79935-3621-4467-94b9-c4da61aa806e'	System	06 Mar 2021 12:47:13
User entered 'Yes (Y)'	System	06 Mar 2021 12:47:13

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Please 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 (2258215eb75c01d8)', Time: '2021-03-06T06:46:48-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '43a79935-3621-4467-94b9-c4da61aa806e'	System	06 Mar 2021 12:47:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Mar 2021 12:47:13

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-03-06T06:47:02-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '43a79935-3621-4467-94b9-c4da61aa806e'	System	06 Mar 2021 12:47:13
User entered '06 Mar 2021 06:47:02'	System	06 Mar 2021 12:47:13

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-03-13T06:46:11-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '0609b527-a13f-4615-86ec-035654fa5a65'	System	13 Mar 2021 12:46:27
User entered 'No (N)'	System	13 Mar 2021 12:46:27

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-03-13T06:46:20-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '0609b527-a13f-4615-86ec-035654fa5a65'	System	13 Mar 2021 12:46:27
User entered 'No (N)'	System	13 Mar 2021 12:46:27

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-03-13T06:46:26-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '0609b527-a13f-4615-86ec-035654fa5a65'	System	13 Mar 2021 12:46:27
User entered '13 Mar 2021 06:46:26'	System	13 Mar 2021 12:46:27

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-03-20T00:01:23-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '77c490e6-9fa0-401d-931c-90f3416f7a31'	System	20 Mar 2021 05:01:31
User entered 'No (N)'	System	20 Mar 2021 05:01:31



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-03-20T00:01:25-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '77c490e6-9fa0-401d-931c-90f3416f7a31'	System	20 Mar 2021 05:01:31
User entered 'No (N)'	System	20 Mar 2021 05:01:31

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-03-20T00:01:29-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '77c490e6-9fa0-401d-931c-90f3416f7a31'	System	20 Mar 2021 05:01:31
User entered '20 Mar 2021 00:01:29'	System	20 Mar 2021 05:01:31

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-03-29T18:30:29-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '33f1bc47-ca67-4cc8-84ef-fc873feb9c99'	System	29 Mar 2021 23:30:39
User entered 'No (N)'	System	29 Mar 2021 23:30:39

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-03-29T18:30:32-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '33f1bc47-ca67-4cc8-84ef-fc873feb9c99'	System	29 Mar 2021 23:30:39
User entered 'No (N)'	System	29 Mar 2021 23:30:39

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-03-29T18:30:34-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '33f1bc47-ca67-4cc8-84ef-fc873feb9c99'	System	29 Mar 2021 23:30:39
User entered '29 Mar 2021 18:30:34'	System	29 Mar 2021 23:30:39



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-04-07T19:47:57-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'daf477ef-f257-44a9-9784-b2528077823f' User entered 'No (N)'	System	08 Apr 2021 00:48:07

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-04-07T19:47:58-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'daf477ef-f257-44a9-9784-b2528077823f'	System	08 Apr 2021 00:48:07
User entered 'No (N)'	System	08 Apr 2021 00:48:07

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-04-07T19:48:02-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: 'daf477ef-f257-44a9-9784-b2528077823f'	System	08 Apr 2021 00:48:07
User entered '07 Apr 2021 19:48:02'	System	08 Apr 2021 00:48:07

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:11:01



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-04-12T18:30:32-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '716733a6-3202-42f1-87a4-660344009f76'	System	12 Apr 2021 23:30:46
User entered 'No (N)'	System	12 Apr 2021 23:30:46

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-04-12T18:30:33-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '716733a6-3202-42f1-87a4-660344009f76'	System	12 Apr 2021 23:30:46
User entered 'No (N)'	System	12 Apr 2021 23:30:46

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-04-12T18:30:36-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '716733a6-3202-42f1-87a4-660344009f76'	System	12 Apr 2021 23:30:46
User entered '12 Apr 2021 18:30:36'	System	12 Apr 2021 23:30:46

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-04-17T06:30:59-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3dc4bc-cdf5-4e25-aaef-d352212113ac'	System	17 Apr 2021 11:31:14
User entered 'No (N)'	System	17 Apr 2021 11:31:14



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-04-17T06:31:03-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3dc4bc-cdf5-4e25-aaef-d352212113ac'	System	17 Apr 2021 11:31:14
User entered 'No (N)'	System	17 Apr 2021 11:31:14

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-04-17T06:31:08-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8e3dc4bc-cdf5-4e25-aaef-d352212113ac'	System	17 Apr 2021 11:31:14
User entered '17 Apr 2021 06:31:08'	System	17 Apr 2021 11:31:14

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-04-27T14:07:15-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8757642f-0468-48be-8d90-3451e232fcca' User entered 'No (N)'	System	29 Apr 2021 06:42:40
	System	29 Apr 2021 06:42:40

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-04-27T14:07:17-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8757642f-0468-48be-8d90-3451e232fcca' User entered 'No (N)'	System	29 Apr 2021 06:42:40
	System	29 Apr 2021 06:42:40

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-04-27T14:07:20-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '8757642f-0468-48be-8d90-3451e232fcca' User entered '27 Apr 2021 14:07:20'	System	29 Apr 2021 06:42:40
	System	29 Apr 2021 06:42:40



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[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 (2258215eb75c01d8)', Time: '2021-05-01T06:26:16-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '09b0112a-c993-4c81-b2a6-2ec237cfc209'	System	01 May 2021 11:26:23
User entered 'No (N)'	System	01 May 2021 11:26:23

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

Have you been exposed to someone with 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 (2258215eb75c01d8)', Time: '2021-05-01T06:26:18-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '09b0112a-c993-4c81-b2a6-2ec237cfc209'	System	01 May 2021 11:26:23
User entered 'No (N)'	System	01 May 2021 11:26:23

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-05-01T06:26:20-05:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '09b0112a-c993-4c81-b2a6-2ec237cfc209'	System	01 May 2021 11:26:23
User entered '01 May 2021 06:26:20'	System	01 May 2021 11:26:23

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:11:01



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:11:01

**US3042262**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:11:01



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:11:01



**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:11:01

**US3042262**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:55:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:01
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:11:01

US3042262

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:55:45**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-03-01T14:52:39-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2902df36-c552-4663-bb9a-6d4d6ea151ac'	System	01 Mar 2021 20:52:44
User entered 'No (N)'	System	01 Mar 2021 20:52:44



**US3042262**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:28:31
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2258215eb75c01d8)', Time: '2021-03-01T14:52:41-06:00', User OID: 'PatientReportedOutcome (US3042262)', ODM File OID: '2902df36-c552-4663-bb9a-6d4d6ea151ac'	System	01 Mar 2021 20:52:44
User entered '01 Mar 2021 14:52:41'	System	01 Mar 2021 20:52:44

**US3042262**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:19
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:32

**US3042262**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:19
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:32

**US3042262**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:19
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:32

**US3042262**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:19
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:32

US3042262

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:19
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:28:38

**US3042262**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:19
User entered 'I'	System	10 Nov 2020 18:28:38

**US3042262**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:50
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:51:48



**US3042262**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:50
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:51:48

**US3042262**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:50
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:51:48

**US3042262**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:50
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:51:48

**US3042262**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:50
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:51:55

**US3042262**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:50
User entered 'I'	System	15 Dec 2020 16:51:55

**US3042262**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:36
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:24:58

US3042262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:36
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:24:58

US3042262

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:36
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:24:58



**US3042262**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:36
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 22:24:58

US3042262

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:36
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:13:06

**US3042262**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:36
User entered 'I'	System	11 Feb 2021 20:13:06

**US3042262**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:00
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:13:15

**US3042262**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:00
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:13:15

**US3042262**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:00
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:13:15

**US3042262**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:00
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:13:15

**US3042262**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:00
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:13:19



**US3042262**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:00
User entered 'I'	System	11 Feb 2021 20:13:19

US3042262

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:04:18

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '04 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:04:18

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:04:18

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User entered 'VISIT4'	(b) (4), (b) (6) System	09 Mar 2021 15:04:18

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52



US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:59:52

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:59:52

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:59:52



US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:59:52

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:59:52

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:59:52

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:50:22

US3042262

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:50:22

US3042262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:04:38

US3042262

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:04:38



US3042262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:04:45

US3042262

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '04 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:04:45

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:45**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '15:29'	(b) (4) Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:04:45

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User entered '04 Mar 2021 15:29'	(b) (4), (b) (6) System	09 Mar 2021 15:04:45

US3042262

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 15:04:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 15:04:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	09 Mar 2021 15:04:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 15:04:47
User entered empty.	Rylea Gulick (b) (4)	09 Mar 2021 15:04:47
	(b) (4)	

**US3042262**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:22
User entered '1'	(b) (4), (b) (6)	09 Mar 2021 15:04:50
User entered empty.	System	09 Mar 2021 15:04:47

**US3042262**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:35:00

**US3042262**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:35:00



**US3042262**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:55:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:35:00

US3042262

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:55:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:35:00

US3042262

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:55:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:35:09

**US3042262**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:35:09

**US3042262**

**Folder: Covid-19 Assessment 07 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:55:45**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '07 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:08:39

**US3042262**

**Folder: Covid-19 Assessment 07 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:55:45**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '08:23'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:08:39

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:45

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '07 Oct 2020 08:23'	(b) (4), (b) (6) System	07 Oct 2020 14:08:39

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:55:45

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:08:39



**US3042262**

**Folder: Covid-19 Assessment 07 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:55:45**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:08:39

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change:	Rylea Gulick (b) (4)	04 Nov 2020 22:28:11
Data Entry Error	(b) (4)	
User entered 'Day 1 (Day 1)'	Rylea Gulick (b) (4)	07 Oct 2020 14:10:03
	(b) (4)	

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '07 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '98'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '%'	(b) (4), (b) (6) System	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '37.5' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:10:03

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Day 8 (Day 8)' reason for change:	Rylea Gulick (b) (4)	04 Nov 2020 22:28:11
Data Entry Error	(b) (4)	
User entered 'Day 2 (Day 2)'	Rylea Gulick (b) (4)	12 Oct 2020 14:18:40
	(b) (4)	



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '08 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '99'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '%'	(b) (4), (b) (6) System	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '98.2' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	12 Oct 2020 14:19:35
	(b) (4)	
User entered 'Mild (Mild)'	Rylea Gulick (b) (4)	12 Oct 2020 14:18:40
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:18:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Day 9 (Day 9)' reason for change:	Rylea Gulick (b) (4)	04 Nov 2020 22:28:11
Data Entry Error	(b) (4)	
User entered 'Day 3 (Day 3)'	Rylea Gulick (b) (4)	12 Oct 2020 14:19:35
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '09 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '97'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '%'	(b) (4), (b) (6) System	12 Oct 2020 14:19:35

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '97.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:19:35

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Day 10 (Day 10)' reason for change:	Rylea Gulick (b) (4)	04 Nov 2020 22:28:11
Data Entry Error	(b) (4)	
User entered 'Day 4 (Day 4)'	Rylea Gulick (b) (4)	12 Oct 2020 14:20:38
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '10 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '98'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '%'	(b) (4), (b) (6) System	12 Oct 2020 14:20:38



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '98.2' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:20:38

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Day 1 (Day 1)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '01 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User closed query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1, 3, 5, and 6. If not collected, please consider recording these as Not Done. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 10:20:59
Query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1, 3, 5, and 6. If not collected, please consider recording these as Not Done. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 23:37:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 23:37:23
User opened query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1, 3, 5, and 6. If not collected, please consider recording these as Not Done. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 22:50:07
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '%'	(b) (4), (b) (6)	06 Jan 2021 23:37:23
User entered empty.	System	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	06 Jan 2021 23:37:23
change Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	04 Nov 2020 22:26:40
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Day 2 (Day 2)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '02 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered empty.	(b) (4), (b) (6) System	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Day 3 (Day 3)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '03 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	06 Jan 2021 23:37:49
change Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	04 Nov 2020 22:26:40
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '%'	(b) (4), (b) (6)	06 Jan 2021 23:37:49
User entered empty.	System	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	06 Jan 2021 23:37:49
change Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	04 Nov 2020 22:26:40
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Day 4 (Day 4)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '04 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered empty.	(b) (4), (b) (6) System	04 Nov 2020 22:26:40



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:26:40

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Day 5 (Day 5)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '05 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	06 Jan 2021 23:37:59
change Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	04 Nov 2020 22:27:17
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '%'	(b) (4), (b) (6)	06 Jan 2021 23:37:59
User entered empty.	System	04 Nov 2020 22:27:17

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	06 Jan 2021 23:37:59
change Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	04 Nov 2020 22:27:17
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:17

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Day 6 (Day 6)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51



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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '06 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

**US3042262**

**Folder: Covid-19 Assessment 07 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 09 Jun 2021 14:55:45**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	06 Jan 2021 23:37:59
change Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	04 Nov 2020 22:27:51
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '%'	(b) (4), (b) (6)	06 Jan 2021 23:37:59
User entered empty.	System	04 Nov 2020 22:27:51

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	06 Jan 2021 23:37:59
change Data Entry Error	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	04 Nov 2020 22:27:51
	(b) (4)	

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Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:55:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:27:51

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '07 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:09:01

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

[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 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:09:01

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

[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 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:09:01



US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '07 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:09:01

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:09:01

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:09:01

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

[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 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:09:01

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:09:01

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:09:01

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:55:45

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User entered '0'	(b) (4), (b) (6) System	07 Oct 2020 14:09:01

US3042262

Folder: Covid-19 Assessment 07 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:55:45

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:28:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:13:02



US3042262

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:55:45

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:30:18
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'ENTRY UPDATED ' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	29 Oct 2020 18:04:22
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:17:06
User accepted default value 'Day 3 (Day 3)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

US3042262

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:55:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	29 Oct 2020 18:04:19
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Rylea Gulick (b) (4)	12 Oct 2020 14:21:22
	(b) (4)	

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16 Oct 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	29 Oct 2020 18:04:19
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	12 Oct 2020 14:21:22
	(b) (4)	

US3042262

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:55:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

US3042262

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:55:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22



**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

US3042262

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:55:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

US3042262

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:55:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:55:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

US3042262

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:55:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22



US3042262

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:55:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

US3042262

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:55:45

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:22

**US3042262**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	07 Oct 2020 13:52:03
	(b) (4)	

**US3042262**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '07 Oct 2020'	Rylea Gulick (b) (4)	07 Oct 2020 13:52:03
	(b) (4)	

**US3042262**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[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 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:03



**US3042262**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User entered 'SICKD1'	(b) (4), (b) (6) System	07 Oct 2020 13:52:03

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:29

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '07 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:29

**US3042262**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '08:23'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:29

**US3042262**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User entered '07 Oct 2020 08:23'	(b) (4), (b) (6) System	07 Oct 2020 13:52:29

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '185.4' cm	(b) (4) Rylea Gulick (b) (4)	07 Oct 2020 13:52:29
DataPoint set to visible.	(b) (4) System	07 Oct 2020 13:52:03

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '140.5' kg	Rylea Gulick (b) (4)	07 Oct 2020 13:52:29
	(b) (4)	
DataPoint set to visible.	System	07 Oct 2020 13:52:03

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '37.5' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:29



US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:29

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	07 Oct 2020 13:52:29
	(b) (4)	

**US3042262**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '123'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:29

**US3042262**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User entered 'bpm'	(b) (4), (b) (6) System	07 Oct 2020 13:52:29

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:29

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User entered 'breaths/min'	(b) (4), (b) (6) System	07 Oct 2020 13:52:29

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '133'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:29

**US3042262**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:55:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User entered 'mmHg'	(b) (4), (b) (6) System	07 Oct 2020 13:52:29



US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '84'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:29

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User entered 'mmHg'	(b) (4), (b) (6) System	07 Oct 2020 13:52:29

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:16:59

US3042262

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:55:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:16:59

US3042262

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:33

US3042262

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:55:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '07 Oct 2020'	Rylea Gulick (b) (4)	07 Oct 2020 13:52:33
	(b) (4)	

US3042262

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:55:45

[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 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:43

US3042262

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:55:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
User entered '07 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 13:52:43



US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:55:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 21:00:17
	(b) (4)	

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 21:00:17
	(b) (4)	

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[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 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Clinic (Clinic)'	Jessica Knight (b) (4)	16 Jan 2021 21:00:17
	(b) (4)	

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:55:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 21:00:17

US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:45

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 21:00:32
	(b) (4)	

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:45**

[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 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Apr 2021 18:39:19
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:22:01

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:45**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 21:00:32
	(b) (4)	

US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
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)	12 Apr 2021 11:19:30
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 18:39:23
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 18:39:19
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 17:06:52
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:22:01



US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 21:00:32
	(b) (4)	

US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Jessica Knight (b) (4)	16 Jan 2021 21:00:32
	(b) (4)	

US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 07:55:21
User entered 'mRNA-1273 (mRNA-1273)'	Jessica Knight (b) (4)	16 Jan 2021 21:00:32
	(b) (4)	

US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:55:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 07:55:21
User entered 'mRNA-1273 (mRNA-1273)'	Jessica Knight (b) (4)	16 Jan 2021 21:00:32
	(b) (4)	

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:45**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'No (N)'	Jessica Knight (b) (4)	16 Jan 2021 21:00:32
	(b) (4)	

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:45**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
User entered empty.	(b) (4), (b) (6) System	16 Jan 2021 21:00:32

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:55:45**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
User entered empty.	(b) (4), (b) (6) System	16 Jan 2021 21:00:32

US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 21:00:50
	(b) (4)	



US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 21:00:50
	(b) (4)	

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:55:45**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '08:53'	Jessica Knight (b) (4)	16 Jan 2021 21:00:50
	(b) (4)	

US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:55:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
User entered '16 Jan 2021 08:53'	(b) (4), (b) (6)	16 Jan 2021 21:00:50
	System	

US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Jessica Knight (b) (4)	16 Jan 2021 21:00:59
	(b) (4)	

US3042262

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:55:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '16 Jan 2021'	Jessica Knight (b) (4)	16 Jan 2021 21:00:59
	(b) (4)	

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:55:45**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered '08:55'	Jessica Knight (b) (4)	16 Jan 2021 21:00:59
	(b) (4)	

**US3042262**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:55:45**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:01
User entered '16 Jan 2021 08:55'	(b) (4), (b) (6)	
	System	16 Jan 2021 21:00:59

US3042262

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:55:45

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:12:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:23:38
User closed query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:46:49
Query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'no ae was necessary. follow up was made' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	29 Mar 2021 18:45:46
User opened query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 03:52:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 14:21:46
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 14:57:38



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6) Jessica Knight (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	(b) (4) Jessica Knight (b) (4)	22 Nov 2020 16:48:05

US3042262

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Nov 2020 16:50:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Nov 2020 16:50:00
Data point term sent to Coder	System	22 Nov 2020 16:49:13
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
Data point term sent to Coder	System	22 Nov 2020 16:48:10
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:30:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 18:30:39
Data point term sent to Coder	System	10 Nov 2020 18:29:46
User entered 'WORSENING DEPRESSION'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered '1 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:05
	(b) (4)	
User entered empty.	System	10 Nov 2020 18:29:37



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:27
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
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	12 Jan 2021 23:04:33
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	12 Jan 2021 23:04:33
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	12 Jan 2021 23:04:27
User entered '12 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:27
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:05
	(b) (4)	
User entered empty.	System	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'Per DM CLR - RQ: Site's response noted. However, ongoing MH condition is considered MILD by default. If this AE is a worsening of the MH condition, it is unexpected to MILD. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 14:08:28
Query 'Per DM CLR - RQ: Site's response noted. However, ongoing MH condition is considered MILD by default. If this AE is a worsening of the MH condition, it is unexpected to MILD. Please review and update the grade or provide clarification. ' answered with 'per PI, THIS IS GRADE 1' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:00:00
User opened query 'Per DM CLR - RQ: Site's response noted. However, ongoing MH condition is considered MILD by default. If this AE is a worsening of the MH condition, it is unexpected to MILD. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 06:21:35
User closed query 'Per DM CLR: Please review Severity and please note that a worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update Severity as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:16:02
Query 'Per DM CLR: Please review Severity and please note that a worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update Severity as appropriate. Otherwise, clarify.' answered with 'Grade 1 per PI' (Site from DM).	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:49:07
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Severity](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review Severity and please note that a worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update Severity as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:35:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:29:37



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:29:37



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 18:30:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 18:30:15
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Nov 2020 18:30:15
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 18:29:37
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 18:30:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 18:30:15
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Nov 2020 18:30:15
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 18:29:37
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 18:30:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 18:30:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 18:30:15
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 18:29:37
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:33
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	10 Nov 2020 18:29:37



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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 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:15
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:48:05
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:05
	(b) (4)	
User entered '0'	System	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:05
	(b) (4)	
User entered '1'	System	10 Nov 2020 18:29:37

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:55:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:49
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:15
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jessica Knight (b) (4)	22 Nov 2020 16:48:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:07:59

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'Per MM: please confirm if a more specific diagnosis was identified. If yes, please update event term' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 13:45:42
User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 23:43:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 23:43:34
Data point term sent to Coder	System	02 Feb 2021 23:42:31
Query 'Per MM: please confirm if a more specific diagnosis was identified. If yes, please update event term' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Feb 2021 23:42:22
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	02 Feb 2021 23:42:06
User entered 'VIRAL SYNDROME OF UNKNOWN ETIOLOGY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Feb 2021 23:42:06
User opened query 'Per MM: please confirm if a more specific diagnosis was identified. If yes, please update event term' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 13:11:58
User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 16:44:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 16:44:59
Data point term sent to Coder	System	14 Dec 2020 16:01:22
User entered 'COVID-LIKE ILLNESS'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07



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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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Folder: Adverse Events

Form: Adverse Events (12)

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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)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '01 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 16:01:07

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '13 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07



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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

US3042262

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

US3042262

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

US3042262

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07



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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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Folder: Adverse Events

Form: Adverse Events (12)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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Folder: Adverse Events

Form: Adverse Events (12)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

US3042262

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Not Related (NOT RELATED)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07



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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#15) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:57:31
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#15) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 16:14:33
User entered '0' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 16:14:29
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#15) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 04:36:58
User entered '1'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #15 indication is different from this AE term. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 02:24:11
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #15 indication is different from this AE term. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	15 Feb 2021 14:49:20
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #15 indication is different from this AE term. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 01:34:46
User entered '1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 16:14:29
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

US3042262

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 14:55:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[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 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User entered '0'	(b) (4), (b) (6) System	14 Dec 2020 16:01:07

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:07:59
User entered '0'	(b) (4), (b) (6) System	14 Dec 2020 16:01:07



**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (12)**

**Generated On: 09 Jun 2021 14:55:45**

[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 18:07:59

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:08:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Slipped lumbar disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 11:11:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 11:11:58
Data point term sent to Coder	System	12 Jan 2021 23:04:31
User entered 'L5 SLIPPED DISC'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '04 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01



**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User entered empty.	(b) (4), (b) (6) System	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Feb 2021 14:44:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

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**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '20 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Feb 2021 14:44:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User entered empty.	(b) (4), (b) (6) System	12 Jan 2021 23:04:01

US3042262

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 19:24:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Jan 2021 19:24:42
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 19:24:42
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 23:04:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

US3042262

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01



**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

US3042262

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01



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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:55:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 19:24:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Jan 2021 19:24:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 19:24:42
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 23:04:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

US3042262

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 19:24:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Jan 2021 19:24:42
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 19:24:42
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 23:04:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

US3042262

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

US3042262

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
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. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 14:11:34
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'CON MED WILL BE UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:00:57
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. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 06:21:53
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

US3042262

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 14:55:45

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Feb 2021 14:44:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01



**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[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 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User entered '0'	(b) (4), (b) (6) System	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:06
User entered 'I'	(b) (4), (b) (6) System	12 Jan 2021 23:04:01

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (13)**

**Generated On: 09 Jun 2021 14:55:45**

[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 18:08:06

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 15:11:56
User entered	System	10 Mar 2021 19:53:18
'USA-US052-2021-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	10 Mar 2021 19:53:18

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Intentional self-injury, LLT: Deliberate self-harm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:46:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:46:01
Data point term sent to Coder	System	11 Mar 2021 19:38:05
Coding entries removed.	Jamie Thompson (b) (4) (b) (4)	11 Mar 2021 19:37:58
User entered 'Act of Self-Harm' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	11 Mar 2021 19:37:58
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicide attempt, LLT: Suicide attempt - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:01:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:01:56
Data point term sent to Coder	System	09 Mar 2021 15:01:23
User entered 'SUICIDE ATTEMPT'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31



**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '24 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:00:31

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '24 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31



**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 19:39:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:39:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:39:23
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 15:00:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
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)	10 Mar 2021 19:52:08
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 'ENTRY UPDATED' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:39:33
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)	09 Mar 2021 22:05:12
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31



**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 19:52:18
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'ENTRY UPDATED' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:39:40
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 19:39:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:39:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:39:23
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 22:04:53
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 15:00:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 19:39:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 19:39:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:39:23
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 15:00:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31



**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User closed query 'PV Query: Please provide 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)	22 Mar 2021 18:22:32
Query 'PV Query: Please provide 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 'CON MED HAS BEEN UPDATED WITH MEDICATION.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 19:59:11
User opened query 'PV Query: Please provide 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)	16 Mar 2021 12:59:34
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

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 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

US3042262

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 14:55:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:24:09
User entered 'Patient had suicidal ideations and began cutting hand; patient stopped when saw blood. Patient did not seek medical attention for cut. Patient saw PCP one week after incident and was not hospitalized; PI determined this was an act of self-harm, not an attempt at suicide.' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	11 Mar 2021 19:37:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Mar 2021 15:01:02
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Mar 2021 15:01:02
User entered 'SUBJECT HAD A SUICIDE ATTEMPT.' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:01:02
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Mar 2021 15:00:31
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:00:31

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Mar 2021 15:00:31

**US3042262**

**Folder: Adverse Events**

**Form: Adverse Events (14)**

**Generated On: 09 Jun 2021 14:55:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Mar 2021 15:00:31



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:55:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:12:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 15:25:26
	(b) (4)	

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:27:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:27:21
Data point term sent to Coder	System	21 Aug 2020 15:26:19
User entered 'BUPROPION'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'DEPRESSION'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '300'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'UN UNK 2019'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:25:47



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:25:47

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:25:47

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:25:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:27:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:27:20
Data point term sent to Coder	System	21 Aug 2020 15:26:19
User entered 'BUSPIRONE'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '10'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'three times daily (TID)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'UN UNK 2019'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:09

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Aug 2020 15:26:09

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:26:09

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:26:09

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: METHYLPHENIDATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:28:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:28:23
Data point term sent to Coder	System	21 Aug 2020 15:27:20
User entered 'METHYLPHENIDATE'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ATTENTION DEFICIT HYPERACTIVE DISORDER'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '30'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'UN Feb 2020'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:38

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:26:38

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:26:38

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:26:38

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:28:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:28:22
Data point term sent to Coder	System	21 Aug 2020 15:27:21
User entered 'TRAZODONE'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'INSOMNIA'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '100'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'UN Feb 2020'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:26:54

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:26:54

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:26:54



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:26:54

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA D - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:28:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:28:23
Data point term sent to Coder	System	21 Aug 2020 15:27:23
User entered 'ALLEGRA D'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'SEASONAL ALLERGIES'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '120/60'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'twice daily (BID)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'UN Mar 2020'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:27:17



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 15:27:17

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:27:17

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:27:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:49:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:49:34
Data point term sent to Coder	System	21 Aug 2020 15:29:30
User entered 'MONTELUKAST'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'SEASONAL ALLERIGES'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '10'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'UN Apr 2020'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:01

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:29:01

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:29:01

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:29:01

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:30:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:30:14
Data point term sent to Coder	System	21 Aug 2020 15:29:30
User entered 'CLONIDINE'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '.05'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'UN Oct 2019'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:23

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:29:23

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:29:23

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:29:23

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLUTICASON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:33:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:33:33
Data point term sent to Coder	System	21 Aug 2020 15:30:31
User entered 'FLUTICASON'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'SEASONAL ALLERGIES'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '50'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ug (ug)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Nasal (NASAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'UN UNK 2014'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:29:46

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:29:46

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:29:46



US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:29:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: PROAIR [SALBUTAMOL SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:32:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:32:21
Data point term sent to Coder User entered 'PROAIR'	System Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:35 21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ASTHMA'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '90'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ug (ug)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'UN UNK 2010'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:10



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:30:10

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:30:10

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:30:10

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: HYPNOTICS AND SEDATIVES IN COMBINATION, EXCL. BARBITURATES, PRODUCT: MATRICARIA RECUTITA FLOWER;MELATONIN;MELISSA OFFICINALIS HERB;PASSIFLORA INCARNATA HERB;THEANINE, PRODUCTSYNONYM: OLLY RESTFUL SLEEP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 09:08:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 09:08:43
Data point term sent to Coder	System	21 Aug 2020 15:30:36
User entered 'OLLY SLEEP'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'INSOMNIA'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '5'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 15:59:30
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 14:48:16
User entered 'UN Feb 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 14:47:48
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:39:56
User entered 'UN Jan 2020'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:30:28

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:30:28

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:30:28

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:30:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDs, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:26:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:26:42
Data point term sent to Coder	System	21 Aug 2020 15:31:37
User entered 'PREDNISONE'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'BELLS PALSY'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:55:45**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '20'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:55:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '08 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '18 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:55:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 15:31:06

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:22
User entered '804 (804)'	(b) (4), (b) (6) System	21 Aug 2020 15:31:06

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:03:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 11:03:40
Data point term sent to Coder	System	21 Aug 2020 15:32:40
User entered 'VALACYCLOVIR'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'BELLS PALSY'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'g (g)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '08 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:55:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '15 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 15:31:47



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:55:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:33:50
User entered '804 (804)'	(b) (4), (b) (6) System	21 Aug 2020 15:31:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:42:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 23:42:17
Data point term sent to Coder	System	21 Aug 2020 15:32:40
User entered 'BACLOFEN'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'BELLS PALSY'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '10'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '08 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '13 Jul 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 15:32:11



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:55:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:20
User entered '804 (804)'	(b) (4), (b) (6) System	21 Aug 2020 15:32:11

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
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)	25 Sep 2020 06:56:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:56:47
Data point term sent to Coder	System	24 Sep 2020 21:04:00
User entered 'IBUPROFEN'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:09:18
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria. ' answered with 'headache did not meet ae reporting criteria' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 20:08:43

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the Headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Headache did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 09:19:46
User entered 'SOLICITED SYMPTOM-HEADACHES'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '200'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '18 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:55:45**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '18 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:55:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 21:03:40

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:34:52
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 21:03:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEP HRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 08:39:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 08:39:57
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	15 Feb 2021 14:49:58 15 Feb 2021 14:49:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEP HRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 16:00:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 16:00:47
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 15:58:20 14 Dec 2020 15:58:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEP HRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:54:22

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:54:22
Data point term sent to Coder	System	06 Nov 2020 22:30:49
User closed query 'For coding purposes, references indicate different formulations for DAYQUIL. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	06 Nov 2020 22:30:08
Query 'For coding purposes, references indicate different formulations for DAYQUIL. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'ENTRY UPDATED' (Site from System).	Rylea Gulick (b) (4)	06 Nov 2020 22:30:08
Coding entries removed.	Rylea Gulick (b) (4)	06 Nov 2020 22:30:00
User entered 'DAYQUIL [ACETAMINOPHEN, DEXTROMETHORPHEN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE]' reason for change: Data Entry Error	Rylea Gulick (b) (4)	06 Nov 2020 22:30:00
User opened query 'For coding purposes, references indicate different formulations for DAYQUIL. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4)	06 Nov 2020 17:38:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:31:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:31:38
Data point term sent to Coder	System	04 Nov 2020 22:31:02
Coding entries removed.	Rylea Gulick (b) (4)	04 Nov 2020 22:30:20



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:15:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:15:47
Data point term sent to Coder	System	07 Oct 2020 14:21:23
User entered 'DAYQUIL'	Rylea Gulick (b) (4)	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 01:44:40
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'START DATE IS CORRECT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:01:53
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:16:55
User entered 'VIRAL SYNDROME OF UNKNOWN ETIOLOGY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Feb 2021 14:49:04
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 17:32:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 15:59:41
User entered 'COVID-LIKE ILLNESS' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 15:58:07

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 14:50:14
User entered 'SORE THROAT, NASAL CONGESTION, RUNNY NOSE' reason for change: Data Entry Error	Rylea Gulick (b) (4)	04 Nov 2020 22:30:20
User entered 'SOLICITED SYMPTOMS-SORE THROAT, NASAL CONGESTION, RUNNY NOSE'	(b) (4)	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 17:32:21
Query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Update as appropriate.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:00:12
User entered '325/10/5' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:00:05
User opened query 'Per DM CLR: For medications with multiple components, please review if the number of ML would be a more appropriate dose. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 14:52:36
User entered '650'	Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '01 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR re-query: Response is noted, however, a stop date should be recorded for this Con Med as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 01:45:17
Query 'Per DM CLR re-query: Response is noted, however, a stop date should be recorded for this Con Med as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' answered with 'END DATE WILL BE UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:00
User opened query 'Per DM CLR re-query: Response is noted, however, a stop date should be recorded for this Con Med as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 01:52:17
User closed query 'Per CDM, DM CLR re-query: Please provide a stop date or provide clarification for continued use of the medication.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 11:13:43
Query 'Per CDM, DM CLR re-query: Please provide a stop date or provide clarification for continued use of the medication.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 17:06:59
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 17:06:52
User opened query 'Per CDM, DM CLR re-query: Please provide a stop date or provide clarification for continued use of the medication.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 14:15:35
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)	18 Feb 2021 14:15:35

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
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 'WILL BE REVIEWED FOR STOP DATE.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 22:14:32
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)	28 Jan 2021 04:06:22
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '15 Oct 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 17:06:52
User entered empty.	Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:53:50
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:30:13
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:30:08
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 10:37:10
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	07 Oct 2020 14:20:28

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User entered empty.	(b) (4), (b) (6) System	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User entered empty.	(b) (4), (b) (6) System	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:55:45

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:35:25
User entered empty.	(b) (4), (b) (6) System	07 Oct 2020 14:20:28

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DESVENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:38:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:38:42
Data point term sent to Coder	System	10 Nov 2020 18:31:48
User entered 'DESVENLAFAXINE'	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 17:32:41
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:05:11
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 16:05:07
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 14:53:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'WORSENING DEPRESSION'	(b) (4), (b) (6)	10 Nov 2020 18:31:08

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:55:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '50'	(b) (4), (b) (6)	10 Nov 2020 18:31:08



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 18:31:08



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 18:31:08

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 18:31:08

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 18:31:08

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 18:31:08

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 02:22:19
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' answered with 'SUBJECT DID NOT HAVE A WORSENING ON ANXIETY' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	03 Feb 2021 18:47:57
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 04:04:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 16:57:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 16:57:51
Data point term sent to Coder	System	15 Dec 2020 16:56:57
User entered 'ALPRAZOLAM'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 16:56:40



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:45**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ANXIETY'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0.5'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'as needed (PRN)'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 16:56:40



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '11 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 16:56:40

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 16:56:40

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 16:56:40

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 16:56:40

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 16:56:40



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDs, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:39:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:39:03
Data point term sent to Coder	System	25 Jan 2021 17:02:21
User entered 'PREDNISONE'	Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:45**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'L5 SLIPPED DISC'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '20'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'once daily (QD)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Oral (ORAL)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '04 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	25 Jan 2021 17:01:53
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	25 Jan 2021 17:01:46
	(b) (4)	

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	25 Jan 2021 17:01:53
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	25 Jan 2021 17:01:46
User entered '15 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Jan 2021 17:01:46

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User entered '1'	(b) (4), (b) (6) System	25 Jan 2021 17:01:46



**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User entered '1'	(b) (4), (b) (6) System	25 Jan 2021 17:01:46

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:36:13
User entered '804 (804)'	(b) (4), (b) (6) System	25 Jan 2021 17:01:46

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 08 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:02:37
Query 'Per DM CLR: this Con Med was added/ had dose increased on 08 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'SUBJECT DID NOT HAVE WORSENING OR EXACERBATION. SUBJECTS PCP SUGGESTED STARTING MEDICAL MARIJUANA TO HELP ELSE OFF PILLS.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 20:01:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIS SATIVA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:24:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:24:33
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 08 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:27:55
Data point term sent to Coder	System	09 Mar 2021 15:03:25

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:45**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'MEDICAL MARIJUANA CBD/THC'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '215/10'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '08 Mar 2021'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:02:47

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:02:47

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:02:47

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:02:47

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 08 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:03:24
Query 'Per DM CLR: this Con Med was added/ had dose increased on 08 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'THIS WAS NOT A WORSENING OR EXACERBATION. SUBJECTS PCP SUGGESTED MEDICAL MARIJUANA TO HELP EASE OFF PILLS.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 20:01:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIS SATIVA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:24:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:24:33
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 08 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:28:08
Data point term sent to Coder	System	09 Mar 2021 15:03:25
User entered 'MEDICAL MARIJUANA CBD/THC'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '192.61/192.61'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '08 Mar 2021'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:55:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:17

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:03:17

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:03:17

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:03:17

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 08 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). Query 'Per DM CLR: this Con Med was added/ had dose increased on 08 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'THIS IS NOT A WORSENING OR EXACERBATION OF CONDITION. SUBJECTS PCP SUGGESTED MEDICAL MARIJUANA TO HELP EASE OFF PILLS.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:03:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIS SATIVA - version WHODrug-Global-B3\\202003.	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 20:02:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:23:34
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 08 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:23:34
Data point term sent to Coder User entered 'MEDICAL MARIJUANA CBD/THC'	(b) (4), (b) (6)	17 Mar 2021 06:28:32
	System	09 Mar 2021 15:04:25
	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'ANXIETY'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '112/56'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:03:49
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'THIS IS CORRECT' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	19 Mar 2021 20:02:37
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:28:25
User entered 'Topical (TOPICAL)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53



US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '08 Mar 2021'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered '0'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:55:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

US3042262

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:55:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:55:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:58:01
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	09 Mar 2021 15:03:53

**US3042262**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:55:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:03:53

US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:03:53



US3042262

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:55:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 15:03:53

US3042262

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 14:55:45**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 21:36:34
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 14:57:43

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'USA-US052-2021-MRNA-1273-P301000006'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18



**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'David'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Enszt'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User closed query 'Please add address, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:22:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:49
Query 'Please add address, thanks ' answered with 'ENTRY ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:42
User entered '4802 SUNNYBROOK DRIVE'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23
User opened query 'Please add address, thanks ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 15:42:30

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'SIOUX CITY'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'IOWA'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered '51106'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23



**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'US'	System	10 Mar 2021 19:53:37

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:25:21
User entered '3'	System	12 Mar 2021 15:12:30
User entered '2'	System	10 Mar 2021 20:00:40
User entered '1'	System	10 Mar 2021 19:53:37

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'USA-US052-2021-MRNA-1273-P301000006'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18



**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'David'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Enszt'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User closed query 'Please add address, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:22:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:49
Query 'Please add address, thanks ' answered with 'ENTRY ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:42
User entered '4802 SUNNYBROOK DRIVE'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23
User opened query 'Please add address, thanks ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 15:42:30

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'SIOUX CITY'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'IOWA'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered '51106'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23



**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'US'	System	10 Mar 2021 19:53:37

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:25:21
User entered '3'	System	12 Mar 2021 15:12:30
User entered '2'	System	10 Mar 2021 20:00:40
User entered '1'	System	10 Mar 2021 19:53:37

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered '10/Mar/2021 14:53'	System	10 Mar 2021 19:53:37

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:55:45

**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 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 19:53:37

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'USA-US052-2021-MRNA-1273-P301000006'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18



**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'David'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Enszt'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User closed query 'Please add address, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:22:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:49
Query 'Please add address, thanks ' answered with 'ENTRY ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:42
User entered '4802 SUNNYBROOK DRIVE'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23
User opened query 'Please add address, thanks ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 15:42:30

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'SIOUX CITY'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23



**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'IOWA'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered '51106'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'US'	System	10 Mar 2021 19:53:37

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:25:21
User entered '3'	System	12 Mar 2021 15:12:30
User entered '2'	System	10 Mar 2021 20:00:40
User entered '1'	System	10 Mar 2021 19:53:37

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered '10/Mar/2021 15:00'	System	10 Mar 2021 20:00:40

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:55:45

**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 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 20:00:45
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 20:00:40

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'USA-US052-2021-MRNA-1273-P301000006'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18



**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'David'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Enszt'	System	10 Mar 2021 19:53:18



US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User closed query 'Please add address, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:22:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:49
Query 'Please add address, thanks ' answered with 'ENTRY ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:42
User entered '4802 SUNNYBROOK DRIVE'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23
User opened query 'Please add address, thanks ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 15:42:30

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'SIOUX CITY'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'IOWA'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered '51106'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'US'	System	10 Mar 2021 19:53:37

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:25:21
User entered '3'	System	12 Mar 2021 15:12:30
User entered '2'	System	10 Mar 2021 20:00:40
User entered '1'	System	10 Mar 2021 19:53:37

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered '12/Mar/2021 10:12'	System	12 Mar 2021 15:12:30

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:55:45

**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 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 15:12:30



**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'USA-US052-2021-MRNA-1273-P301000006'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'No (N)'	System	10 Mar 2021 19:53:18

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Yes (Y)'	System	10 Mar 2021 19:53:18



US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'David'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'Enszt'	System	10 Mar 2021 19:53:18

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:55:45

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
User closed query 'Please add address, thanks ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:22:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:21:49
Query 'Please add address, thanks ' answered with 'ENTRY ADDED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:42
User entered '4802 SUNNYBROOK DRIVE'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23
User opened query 'Please add address, thanks ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 15:42:30

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'SIOUX CITY'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'IOWA'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered '51106'	Rylea Gulick (b) (4) (b) (4)	01 Apr 2021 18:39:23

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 19:53:41
User entered 'US'	System	10 Mar 2021 19:53:37

**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:55:45**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:25:21
User entered '3'	System	12 Mar 2021 15:12:30
User entered '2'	System	10 Mar 2021 20:00:40
User entered '1'	System	10 Mar 2021 19:53:37



**US3042262**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:55:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered '22/Mar/2021 14:25'	System	22 Mar 2021 18:25:21

US3042262

Folder: SAE USA-US052-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:55:45

**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 21:36:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:21:49
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 18:25:21