

US3042241 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:53:57

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US3042241

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

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Participant ID

US3042241

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

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US3042241

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3042241

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	29
Age Units	YEARS
Age (Derived)	29
Sex	Female <input checked="" type="radio"/> Male <input 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 15:41:35

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	19 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 15:41:35

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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 15:41:35

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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 15:41:35

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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 15:41:35

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Condition	ATTENTION DEFICIT 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: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:41:35

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:38 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:38
Height ( <i>xxx.x</i> )	165.1 cm
Weight ( <i>xxx.x</i> )	86.7 kg
BMI ( <i>xxx.x</i> )	31.80716 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 15:41:35

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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: Childbearing Potential

Data signed: (b) (4) 28 Apr 2021 15:41:35

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Date of assessment (*dd MMM yyyy*) 19 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 15:41:35

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Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 19 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 15:41:35

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**Occupational Risk**

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**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 15:41:35

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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 15:41:35

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What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 105792

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 15:41:35

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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 15:41:35

Generated On: 11 Aug 2021 21:53:57

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)	19 AUG 2020
Time of assessment (00:00-23:59)	13:38 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:38
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)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

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)	19 AUG 2020
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 15:07
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 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 15:41:35

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 15:41:35

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Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 19 AUG 2020

What was the treatment time? (00:00-23:59) 14:32 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 14:32

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 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 AUG 2020

Collection time (00:00-23:59)

14:11 (24 HR)

Collection date and time (derived)

19 AUG 2020 14:11



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:09	19 AUG 2020 14:09
Nasopharyngeal Swab 2	No		

US3042241

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**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

99.2 °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

19 AUG 2020 15:07

PC Open Date & Time

19 AUG 2020 14:52

PC Close Date & Time

19 AUG 2020 17:22

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**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 99.3 °F

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

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

PC Time Stamp	19 AUG 2020 18:26
PC Open Date & Time	19 AUG 2020 18:17
PC Close Date & Time	20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 12:08

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

22 AUG 2020 16:48

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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**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

98.7 °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

23 AUG 2020 12:46

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:53:57

**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

24 AUG 2020 12:00

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**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

19 AUG 2020 15:52

PC Open Date & Time

19 AUG 2020 14:52

PC Close Date & Time

19 AUG 2020 17:22

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**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

19 AUG 2020 18:26

PC Open Date & Time

19 AUG 2020 18:17

PC Close Date & Time

20 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**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

20 AUG 2020 12:09

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

**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

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

**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

22 AUG 2020 16:49

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

**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

23 AUG 2020 12:46

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

**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

24 AUG 2020 12:00

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 7
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	25 AUG 2020 12:00
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**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 ☐

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 15:08
PC Open Date & Time	19 AUG 2020 14:52
PC Close Date & Time	19 AUG 2020 17:22

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**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 ☐

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 18:27
PC Open Date & Time	19 AUG 2020 18:17
PC Close Date & Time	20 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**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 ☒

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:09
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59



US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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 ☒

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:02
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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 ☒

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 16:49
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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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US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:46
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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 ☒

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 12:01
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59



US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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 ☒

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3042241

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3042241

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

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)	16 SEP 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:15
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

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)	16 SEP 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:35
Temperature (xxx.x)	37.3 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)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3042241

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3042241

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	16 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

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) 16 SEP 2020

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

Treatment Date and Time (derived) 16 SEP 2020 12:00

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

US3042241

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 SEP 2020
Collection time (00:00-23:59)	11:37 (24 HR)
Collection date and time (derived)	16 SEP 2020 11:37

US3042241

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	16 SEP 2020 11:30
Nasopharyngeal Swab 2	No		



US3042241

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**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

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

16 SEP 2020 12:32

PC Open Date & Time

16 SEP 2020 12:20

PC Close Date & Time

16 SEP 2020 14:50

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	16 SEP 2020 18:04
PC Open Date & Time	16 SEP 2020 15:45
PC Close Date & Time	17 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:53:57

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 13:24

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °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

19 SEP 2020 12:44

---

PC Open Date & Time

19 SEP 2020 12:00

---

PC Close Date & Time

20 SEP 2020 11:59

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US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:53:57

**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

98.6 °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

20 SEP 2020 20:13

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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**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

98.9 °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

21 SEP 2020 12:02

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

22 SEP 2020 12:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**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

16 SEP 2020 12:33

PC Open Date & Time

16 SEP 2020 12:20

PC Close Date & Time

16 SEP 2020 14:50

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**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

16 SEP 2020 18:05

PC Open Date & Time

16 SEP 2020 15:45

PC Close Date & Time

17 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**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

17 SEP 2020 12:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

**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

18 SEP 2020 13:24

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

**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

19 SEP 2020 12:44

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

**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

20 SEP 2020 20:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

**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

21 SEP 2020 12:03

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

**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

22 SEP 2020 12:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**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 ☐

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 12:33
PC Open Date & Time	16 SEP 2020 12:20
PC Close Date & Time	16 SEP 2020 14:50

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**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 ☐

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 18:06
PC Open Date & Time	16 SEP 2020 15:45
PC Close Date & Time	17 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**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 ☒

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:01
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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 ☒



US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 13:24
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:53:57

**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 ☒

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:44
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:53:57

**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 ☒

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:14
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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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US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:03
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:53:57

**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 ☒



US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:53:57

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:02
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3042241

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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



US3042241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 09:05
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042241

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3042241

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 OCT 2020
Collection time (00:00-23:59)	09:01 (24 HR)
Collection date and time (derived)	14 OCT 2020 09:01

US3042241

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 23:01:04
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3042241

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

26 OCT 2020 19:09:25

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3042241

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

02 NOV 2020 06:44:04

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3042241

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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 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	16 NOV 2020 00:01:27
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59



US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 04:39:26
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 00:01:55

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 01:53:10

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

11 DEC 2020 05:05:30

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 00:01:14
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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 <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)	False
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	True
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	25 DEC 2020 12:32:50
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

03 JAN 2021 13:03:03

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59



US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

09 JAN 2021 19:15:17

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

15 JAN 2021 00:02:00

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

22 JAN 2021 01:42:53

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 08:59:56
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

07 FEB 2021 12:00:21

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 00:01:13
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 07:38:33
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

26 FEB 2021 06:40:34

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59



US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 00:04:09
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

12 MAR 2021 00:03:18

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 09:31:44

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 MAR 2021 12:50:49
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 11:05:33

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

11 APR 2021 12:00:26

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

18 APR 2021 15:30:36

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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

25 APR 2021 12:00:15

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59



US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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 <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	03 MAY 2021 17:59:47
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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 ☐



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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 ☐



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Close Date & Time](#)

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05 OCT 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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°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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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°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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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°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 ☐

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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 ☐



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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22 FEB 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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 ☐

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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 <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"/>



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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08 MAR 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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 ☐

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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11 MAR 2022 00:01

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15 MAR 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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 ☐

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

DAY 593

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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05 APR 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

08 APR 2022 00:01

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12 APR 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

15 APR 2022 00:01

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19 APR 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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



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**Generated On: 11 Aug 2021 21:53:57**

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

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29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

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06 MAY 2022 00:01

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10 MAY 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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31 MAY 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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03 JUN 2022 00:01

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07 JUN 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

**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°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 ☐

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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14 JUN 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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21 JUN 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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 ☐



**US3042241**

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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08 JUL 2022 00:01

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12 JUL 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

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19 JUL 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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°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"/>



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

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

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26 JUL 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3042241**

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

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

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

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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09 AUG 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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16 AUG 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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19 AUG 2022 00:01

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23 AUG 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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26 AUG 2022 00:01

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30 AUG 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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06 SEP 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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09 SEP 2022 00:01

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13 SEP 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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"/>



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3042241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59

**US3042241**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 21:53:57**

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		05 MAR 2021 00:04:17

US3042241

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3042241

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

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

PATIENT IN CONVALESCENT  
PHASE

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3042241

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

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

US3042241

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

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) \_\_\_\_\_

US3042241

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

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.*

US3042241

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	09:50 (24 HR)
Collection date and time (derived)	17 MAR 2021 09:50



US3042241

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:36

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042241

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

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*

US3042241

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:41:35

Generated On: 11 Aug 2021 21:53:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3042241**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

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*

**US3042241**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Date of Contact	23 DEC 2020
Time of Contact	11:35
Date and Time of Contact (derived)	23 DEC 2020 11:35
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	20 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	21 DEC 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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EAB) (1725)

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Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	22 DEC 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 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	37.2 C	
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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	24 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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 (6)

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Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Form: Symptom Log (7)

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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"/>

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	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	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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 (7)

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Nasal Congestion

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (8)

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Generated On: 11 Aug 2021 21:53:57

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 (8)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 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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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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 (8)

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Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Form: Symptom Log (9)

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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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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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 (9)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 15:41:33

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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 (10)

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Generated On: 11 Aug 2021 21:53:57

	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	29 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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 (10)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 type="checkbox"/>
Day 11	<input checked="" 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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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 23 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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 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 (12)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 23 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" 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 23 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
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 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 23 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" 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 23 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.8 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 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 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 (15)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 (16)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021
------	-------------

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

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

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

Temperature	101.0 F
-------------	---------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 23 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 (17)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	99.5 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 (17)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 23 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 (18)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.5 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 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 (18)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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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Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 (19)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.5 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 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 (19)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.5 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 23 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.6 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 23 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 23 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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 JAN 2021
------	-------------

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

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

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

Temperature	97.9 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	11 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.9 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 23 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	12 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 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 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 23 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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	13 JAN 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.4 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 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 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 (25)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 23 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 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 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 23 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 JAN 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.6 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 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 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 JAN 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	96.8 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 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 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 23 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" 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 23 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 JAN 2021
------	-------------

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 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 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

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 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 checked="" type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 JAN 2021
------	-------------

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

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

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

Temperature	98.9 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 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 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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

	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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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Data signed: (b) (4) 28 Apr 2021 15:41:33

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Date of Visit	23 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	23 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_  
End Date \_\_\_\_\_  
Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute Yes ☒ No ☐

If Yes, provide:

Start Date 24 DEC 2020  
End Date 24 DEC 2020  
Heart Rate 137 BPM

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_  
End Date \_\_\_\_\_  
Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_  
End Date \_\_\_\_\_  
PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☒  
No ☐

Date of Assessment

06 JAN 2021

Radiographical Evidence Yes ☒  
No ☐

Date of Assessment

06 JAN 2021

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Date of Contact	30 SEP 2020
Time of Contact	14:17
Date and Time of Contact (derived)	30 SEP 2020 14:17
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>

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

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 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	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	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	36.9 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

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 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	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	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Symptom Day

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

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Form: Symptom Log (3)

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	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	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.8 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 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 (3)

Data signed: (b) (4) 28 Apr 2021 15:41:32

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 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 (3)

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Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

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"/>



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Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	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	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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Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:41:32

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	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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Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 15:41:32

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

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Form: Symptom Log (5)

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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 (5)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	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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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	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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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 15:41:32

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

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

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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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 15:41:32

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	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	98 %	
O2 Saturation Units	%	
Temperature	98.6 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 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 (6)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 15:41:32

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Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

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 (7)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	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	27 SEP 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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 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"/>

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

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"/>



US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	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	28 SEP 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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 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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US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

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"/>

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	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	29 SEP 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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 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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US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Date of Visit	30 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	30 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0



US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

---

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

---

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed: (b) (4) 28 Apr 2021 15:41:34**

**Generated On: 11 Aug 2021 21:53:57**

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

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection**

**Data signed: (b) (4) 28 Apr 2021 15:41:34**

**Generated On: 11 Aug 2021 21:53:57**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	24 DEC 2020
Day 5	Yes	26 DEC 2020
Day 7	Yes	28 DEC 2020
Day 9	Yes	01 JAN 2021
Day 14	Yes	06 JAN 2021
Day 21	No	
Day 28	Yes	20 JAN 2021

US3042241

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3042241

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	30 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:17 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 14:17
Height ( <i>xxx.x</i> )	165.1 cm
Weight ( <i>xxx.x</i> )	86.7 kg
Temperature ( <i>xxx.x</i> )	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	82 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042241

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3042241

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 15:41:34

Generated On: 11 Aug 2021 21:53:57

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 SEP 2020

US3042241

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 DEC 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



US3042241

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	11:45 (24 HR)
Vital Signs Date and Time (derived)	23 DEC 2020 11:45
Height ( <i>xxx.x</i> )	165.1 cm
Weight ( <i>xxx.x</i> )	87.2 kg
Temperature ( <i>xxx.x</i> )	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	100 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042241

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

23 DEC 2020

---

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

---

US3042241

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 15:41:34

Generated On: 11 Aug 2021 21:53:57

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 DEC 2020

US3042241

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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	SICKD28

US3042241

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:41:32

Generated On: 11 Aug 2021 21:53:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	20 JAN 2021
Time of assessment ( <i>00:00-23:59</i> )	08:11 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 08:11
Temperature ( <i>xxx.x</i> )	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	68 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042241

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 JAN 2021

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

US3042241

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

20 JAN 2021

**US3042241**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_



US3042241

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

Form: Unblinding

Generated On: 11 Aug 2021 21:53:57

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

**US3042241**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

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

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

**US3042241**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:53:57**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00 - 23:59</i> )	<hr/>
Collection Date and Time (derived)	<hr/>

US3042241

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3042241

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

AEID	
Adverse event	WORSENING DEPRESSION
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)	30 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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AEID	USA-US052-2021-MRNA-1273-P30 1000002
Adverse event	SYMPTOMATIC COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	20 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	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"/>

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Folder: Adverse Events

Form: Adverse Events (8)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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 (9)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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AEID	
Adverse event	PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 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)	13 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 (9)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 15:40:06

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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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 15:40:06

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	26 DEC	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 (2)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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Name of Medication STRATTERA

Prophylaxis Yes ☐  
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 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 (2)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 DEC 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 (3)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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Name of Medication MIRENA IUD

Prophylaxis Yes ☐  
No ☒

Indication CONTRACEPTION

Dose per administration 52

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

Q5YEARS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

Name of Medication TYLENOL SINUS  
[ACETAMINOPHEN,  
GUAIFENESIN,  
PHENYLEPHRINE]

Prophylaxis Yes ☐  
No ☒

Indication SORE THROAT

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	05 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
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 (5)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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Name of Medication DESVENLAFAXINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING DEPRESSION

Dose per administration 45

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 15:40:06

Generated On: 11 Aug 2021 21:53:57

	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)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 DEC 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 (7)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

Name of Medication PHENYLEPHRINE HCL

Prophylaxis Yes ☐  
No ☒

Indication COVID LIKE SYMPTOMS:  
NASAL CONGESTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 15:40:06

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	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)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication COVID LIKE SYMPTOMS:  
MUSCLE ACHES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

	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)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

	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)	06 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)		12 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"/>

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

	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)	06 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	12 JAN 2021	
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"/>

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

Name of Medication SYMBICORT

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 80/4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

	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)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

Name of Medication ADDERALL XR

Prophylaxis Yes ☐  
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 35

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

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

US3042241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 15:40:06

Generated On: 11 Aug 2021 21:53:57

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3042241

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:53:57

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

US3042241

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:53:57

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 ☐

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

SAEID	USA-US052-2021-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	5

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

SAEID	USA-US052-2021-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	06/JAN/2021 18:45
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.	True



US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

SAEID	USA-US052-2021-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	10/FEB/2021 14:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

SAEID	USA-US052-2021-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	12/FEB/2021 09:24
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

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

SAEID	USA-US052-2021-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	03/MAR/2021 13:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 15:41:34

Generated On: 11 Aug 2021 21:53:57

SAEID	USA-US052-2021-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	09/APR/2021 15:39
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

US3042241 (Prod: Meridian Clinical Research)

**US3042241**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:53:57**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
User entered 'US3042241'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:19:32

**US3042241**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:48:18

**US3042241**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:19:34



US3042241

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:53:57

[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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:48:18

**US3042241**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered 'SCRN'	(b) (4), (b) (6) System	19 Aug 2020 20:48:18

US3042241

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:53:57

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered (b) (6) 1990'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:19:35

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '29'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered 'YEARS'	(b) (4), (b) (6) System	19 Aug 2020 20:48:24

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered '29'	(b) (4), (b) (6) System	19 Aug 2020 19:38:03

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Female (F)'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	



**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'I'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:48:24

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	



**US3042241**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:53:57**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:24
	(b) (4)	

US3042241

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:53:57

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User closed query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Aug 2020 21:13:44
Query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Aug 2020 21:13:44
User opened query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Aug 2020 21:13:40
User entered '19 Aug 2020'	Rylea Gulick (b) (4)	19 Aug 2020 19:38:03
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered 'Aug 2020'	(b) (4), (b) (6) System	19 Aug 2020 19:38:03

**US3042241**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered '2020'	(b) (4), (b) (6) System	19 Aug 2020 19:38:03

**US3042241**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:53:57**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Amendment 2 (2)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 19:38:03

**US3042241**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 19:38:03

**US3042241**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:53:57**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	19 Aug 2020 19:38:03
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:53:57**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 19:38:03



**US3042241**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:53:57**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	19 Aug 2020 19:38:03
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:53:57**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	RWS_ENDPOINT	19 Aug 2020 19:19:34
	ENDPOINT (b) (4)	
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:53:57**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered '1'	(b) (4), (b) (6) System	19 Aug 2020 19:38:09

**US3042241**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 19:38:09

US3042241

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:53:57

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:48:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 20:48:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	19 Aug 2020 20:48:33
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 20:48:30
User entered empty.	Rylea Gulick (b) (4)	19 Aug 2020 20:48:30
	(b) (4)	

US3042241

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:53:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(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)	19 Aug 2020 20:50:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:50:05
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 20:49:11
User entered 'DEPRESSION'	Rylea Gulick (b) (4)	19 Aug 2020 20:48:42
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'UN UNK 2016'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:48:42

**US3042241**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:48:42



**US3042241**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:48:42

**US3042241**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:48:42

**US3042241**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:48:42

**US3042241**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered 'Jan 2016'	(b) (4), (b) (6) System	19 Aug 2020 20:48:42

**US3042241**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered '2016'	(b) (4), (b) (6) System	19 Aug 2020 20:48:42

**US3042241**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered empty.	(b) (4), (b) (6) System	19 Aug 2020 20:48:42

**US3042241**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered empty.	(b) (4), (b) (6) System	19 Aug 2020 20:48:42

US3042241

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:53:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(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 disorder - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:50:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 20:50:05
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 20:49:11
User entered 'ATTENTION DEFICIT DISORDER'	Rylea Gulick (b) (4)	19 Aug 2020 20:49:05
	(b) (4)	



**US3042241**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'UN UNK 2019'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:05

**US3042241**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:05

**US3042241**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:05

**US3042241**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:05

**US3042241**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:05

**US3042241**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered 'Jan 2019'	(b) (4), (b) (6) System	19 Aug 2020 20:49:05

**US3042241**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered '2019'	(b) (4), (b) (6) System	19 Aug 2020 20:49:05

**US3042241**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered empty.	(b) (4), (b) (6) System	19 Aug 2020 20:49:05



**US3042241**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered empty.	(b) (4), (b) (6) System	19 Aug 2020 20:49:05

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:31

US3042241

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Aug 2020 21:13:44
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Aug 2020 21:13:44
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Aug 2020 21:13:40
User entered '19 Aug 2020'	Rylea Gulick (b) (4)	19 Aug 2020 20:49:31
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '13:38'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:31

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered '19 Aug 2020 13:38'	(b) (4), (b) (6) System	19 Aug 2020 20:49:31

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '165.1' cm	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 20:49:31
DataPoint set to visible.	(b) (4) System	19 Aug 2020 19:38:09

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '86.7' kg	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 20:49:31
DataPoint set to visible.	(b) (4) System	19 Aug 2020 19:38:09

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
Amendment Manager: User entered '31.80716'	(b) (4), (b) (6)	
	System	17 Sep 2020 00:14:48
User entered '31.8'	System	19 Aug 2020 20:49:31
DataPoint set to visible.	System	19 Aug 2020 19:38:09



**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	19 Aug 2020 20:49:31
DataPoint set to visible.	System	19 Aug 2020 19:38:09

US3042241

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
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 07:18:00
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 14:34:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:34:42
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 08:51:50
User entered '37.5' C	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:31

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:34:42
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	19 Aug 2020 20:49:31
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:31

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:34:42
change Data Entry Error	(b) (4)	
User entered '88'	Rylea Gulick (b) (4)	19 Aug 2020 20:49:31
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered 'bpm'	(b) (4), (b) (6) System	19 Aug 2020 20:49:31

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:34:42
change Data Entry Error	(b) (4)	
User entered '16'	Rylea Gulick (b) (4)	19 Aug 2020 20:49:31
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered 'breaths/min'	(b) (4), (b) (6) System	19 Aug 2020 20:49:31



**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:34:42
change Data Entry Error	(b) (4)	
User entered '120'	Rylea Gulick (b) (4)	19 Aug 2020 20:49:31
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered 'mmHg'	(b) (4), (b) (6) System	19 Aug 2020 20:49:31

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:34:42
change Data Entry Error	(b) (4)	
User entered '88'	Rylea Gulick (b) (4)	19 Aug 2020 20:49:31
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered 'mmHg'	(b) (4), (b) (6) System	19 Aug 2020 20:49:31

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:43:54

**US3042241**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:43:54

**US3042241**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:34

US3042241

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4) System	30 Sep 2020 21:01:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 21:12:42
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Aug 2020 21:13:44
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Aug 2020 21:13:44
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Aug 2020 21:13:40
User entered '19 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:34



**US3042241**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:53:57**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '19 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:53

**US3042241**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:53

**US3042241**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:53:57**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	19 Aug 2020 20:49:53
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:53:57**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	19 Aug 2020 20:49:53
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:53:57**

*If Surgically sterile, date of surgery (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:53

**US3042241**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:53:57**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:53

**US3042241**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:53:57**

*If Post-menopausal, date of last menstruation (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:49:53

**US3042241**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:53:57**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	19 Aug 2020 20:49:53
	(b) (4)	



**US3042241**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:50:57

US3042241

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:57

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User closed query 'Pregnancy Test is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Aug 2020 21:13:44
Query 'Pregnancy Test is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Aug 2020 21:13:44
User opened query 'Pregnancy Test is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	19 Aug 2020 21:13:40
User entered '19 Aug 2020'	Rylea Gulick (b) (4)	19 Aug 2020 20:50:57
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Urine (URINE)'	Rylea Gulick (b) (4)	19 Aug 2020 20:50:57
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Negative (NEGATIVE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:50:57

**US3042241**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:50:57

US3042241

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:57

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User closed query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed.The urine test time need not be filled in this field, this field is for FSH sample collection.As per the response the FSH collected is NO, kindly remove the date and time. Kindly correct.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 03:56:02
Query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed.The urine test time need not be filled in this field, this field is for FSH sample collection.As per the response the FSH collected is NO, kindly remove the date and time. Kindly correct.' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 13:09:11
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 13:09:07
User opened query 'Per CDM Please note as per the CCGs pgno. 24, only if the FSH sample is collected the date and time needs to be completed.The urine test time need not be filled in this field, this field is for FSH sample collection.As per the response the FSH collected is NO, kindly remove the date and time. Kindly correct.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 03:49:59
User closed query 'Per CDM please note the FSH sample collected is No but the Collection date and time has been reported.Kindly confirm or correct accordingly' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 03:49:59
Query 'Per CDM please note the FSH sample collected is No but the Collection date and time has been reported.Kindly confirm or correct accordingly' answered with 'No FSH collected; time is for urine pregnancy test.' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	29 Aug 2020 18:08:25
User opened query 'Per CDM please note the FSH sample collected is No but the Collection date and time has been reported.Kindly confirm or correct accordingly' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 09:48:23

**US3042241**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:50:57

**US3042241**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	10 Sep 2020 13:09:07
	(b) (4)	
User entered '13:51'	Rylea Gulick (b) (4)	19 Aug 2020 20:50:57
	(b) (4)	



**US3042241**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 13:09:07
User entered '19 Aug 2020 13:51'	System	19 Aug 2020 20:50:57

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

[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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

**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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

**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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

**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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

[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 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	19 Aug 2020 20:51:58
	(b) (4)	

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

[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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

**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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58



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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

[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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

**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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

**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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

**US3042241**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:53:57**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

**US3042241**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:53:57**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	19 Aug 2020 20:51:58
	(b) (4)	



US3042241

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

**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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

[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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

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 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 20:51:58

**US3042241**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:53:57**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	19 Aug 2020 20:51:58
	(b) (4)	

**US3042241**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:53:57**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:43:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	19 Aug 2020 20:51:58
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:13:40
	(b) (4)	

US3042241

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:53:57

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4) System	19 Aug 2020 21:13:44
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	19 Aug 2020 21:13:44
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	19 Aug 2020 21:13:44
User entered '19 Aug 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:13:44
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	19 Aug 2020 21:13:40
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	19 Aug 2020 21:13:40
User entered '19 Apr 2020'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:13:40



**US3042241**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[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 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:13:40

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'VISIT1'	(b) (4), (b) (6) System	19 Aug 2020 21:13:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Aug 2020 21:13:44
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Aug 2020 21:13:44
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Aug 2020 21:13:40
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:19:40

US3042241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:57

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:41:17
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:41:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 19:19:40
User entered '105792' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:19:40
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:53:57

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT	19 Aug 2020 19:19:40
	ENDPOINT (b) (4)	
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:53:57**

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 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:13:54

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:53:57**

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 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:13:54

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:53:57**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:13:54
	(b) (4)	



**US3042241**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:53:57**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:13:54
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:53:57**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:13:54

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:53:57**

**Human Immunodeficiency Virus (HIV) infection**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
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 07:49:10
User entered 'No (N)'	Rylea Gulick (b) (4)	29 Oct 2020 17:47:05
	(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 17:47:02
Amendment Manager: DataPoint set to visible.		29 Oct 2020 14:51:41
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 10:36:12
	System	19 Sep 2020 01:36:36

US3042241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
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 06:06:42
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.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4)	28 Oct 2020 19:45:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:45:48
	(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 04:28:57
User entered '165.1' cm	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:53:57**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:45:48
change Data Entry Error	(b) (4)	
User entered '86.7' kg	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

US3042241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
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 06:06:42
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 19:45:51
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 19:45:48
	(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 04:28:57
User entered '165.1' cm	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

US3042241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:57

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:45:48
change Data Entry Error	(b) (4)	
User entered '86.7' kg	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42



**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '19 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '13:38'	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered '19 Aug 2020 13:38'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

US3042241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '37.5' C	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '88'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42



**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'bpm'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '16'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'breaths/min'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '120'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'mmHg'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '88'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'mmHg'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

US3042241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
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 06:06:42
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.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4)	28 Oct 2020 19:45:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:45:48
	(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 04:28:57
User entered '165.1' cm	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	



US3042241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:53:57

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:45:48
change Data Entry Error	(b) (4)	
User entered '86.7' kg	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

US3042241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '19 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

US3042241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'PER PROTOCOL, SUBJECT ONLY NEEDS TO WAIT 30 MINUTES AFTER VACCINATION BEFORE POST DOSE VITALS ARE TAKEN' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 07:19:13
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	Rylea Gulick (b) (4)	19 Aug 2020 21:14:59
User entered '15:07'	(b) (4)	
	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered '19 Aug 2020 15:07'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

US3042241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '36.7' C	Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42



**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:14:42
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '82'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'bpm'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'breaths/min'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '130'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'mmHg'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '82'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:14:42



**US3042241**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'mmHg'	(b) (4), (b) (6) System	19 Aug 2020 21:14:42

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	19 Aug 2020 21:15:07
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '19 Aug 2020'	Rylea Gulick (b) (4)	19 Aug 2020 21:15:07
	(b) (4)	

US3042241

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:57

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User closed query 'Per CDM please note as Screening and Visit 1 is done on the same date the Pregnancy test in Visit 1 screens to be changed as "NO".Kindly update ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 04:17:13
Query 'Per CDM please note as Screening and Visit 1 Rylea Gulick is done on the same date the Pregnancy test in Visit 1 screens to be changed as "NO".Kindly update ' answered with 'entry updated' (Site from DM).	(b) (4)	10 Sep 2020 13:09:37
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	10 Sep 2020 13:09:33
	(b) (4)	
User opened query 'Per CDM please note as Screening and Visit 1 is done on the same date the Pregnancy test in Visit 1 screens to be changed as "NO".Kindly update ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 04:45:24
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	19 Aug 2020 21:15:22
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty; reason for change Data Entry Error	(b) (4) Rylea Gulick (b) (4)	10 Sep 2020 13:09:33
User entered '19 Aug 2020'	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:15:22
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	10 Sep 2020 13:09:33
	(b) (4)	
User entered 'Urine (URINE)'	Rylea Gulick (b) (4)	19 Aug 2020 21:15:22
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	10 Sep 2020 13:09:33
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Rylea Gulick (b) (4)	19 Aug 2020 21:15:22
	(b) (4)	

US3042241

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:53:57

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User closed query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 05:49:38
Query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	26 Oct 2020 17:16:02
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	26 Oct 2020 17:15:59
User opened query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:04:28
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 13:09:33
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:15:22



**US3042241**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	10 Sep 2020 13:09:33
	(b) (4)	
User entered '19 Aug 2020'	Rylea Gulick (b) (4)	19 Aug 2020 21:15:22
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	10 Sep 2020 13:09:33
	(b) (4)	
User entered '13:51'	Rylea Gulick (b) (4)	19 Aug 2020 21:15:22
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered empty.	(b) (4), (b) (6)	
	System	10 Sep 2020 13:09:33
User entered '19 Aug 2020 13:51'	System	19 Aug 2020 21:15:22

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:53:57**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 19:38:25

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:53:57**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	19 Aug 2020 19:38:25
	(b) (4)	

US3042241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

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 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 19:38:25

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:53:57**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	19 Aug 2020 21:13:44
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Aug 2020 21:13:44
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	19 Aug 2020 21:13:40
User entered '19 Aug 2020'	Rylea Gulick (b) (4)	19 Aug 2020 19:38:25
	(b) (4)	



US3042241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '14:32'	Rylea Gulick (b) (4)	19 Aug 2020 19:38:25
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:53:57**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered '19 Aug 2020 14:32'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 19:38:25
	(b) (4)	

US3042241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'ONCE'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:53:57**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:15:35
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '19 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:15:35

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '14:11'	Rylea Gulick (b) (4)	19 Aug 2020 21:15:35
	(b) (4)	



**US3042241**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered '19 Aug 2020 14:11'	(b) (4), (b) (6) System	19 Aug 2020 21:15:35

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:53:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '19 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:16:02

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	19 Aug 2020 21:16:02

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:16:02

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:53:57**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '14:09'	(b) (4) Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:16:02

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered '19 Aug 2020 14:09'	(b) (4), (b) (6) System	19 Aug 2020 21:16:02

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Rylea Gulick (b) (4)	19 Aug 2020 21:16:02

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:16:02
	(b) (4)	



**US3042241**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:53:57**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4)	19 Aug 2020 21:16:02
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered empty.	(b) (4), (b) (6) System	19 Aug 2020 21:16:02

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	19 Aug 2020 21:16:04
	(b) (4)	

**US3042241**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:55:03
User entered 'I'	(b) (4), (b) (6) System	19 Aug 2020 21:16:04

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:06:58', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3932cc20-2cd9-4f57-a38d-0733dd17cf2a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Aug 2020 20:07:14
	System	19 Aug 2020 20:07:14

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:07:03', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3932cc20-2cd9-4f57-a38d-0733dd17cf2a' User entered '99.2'	(b) (4), (b) (6) System	19 Aug 2020 20:07:14
	System	19 Aug 2020 20:07:14

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:07:07', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3932cc20-2cd9-4f57-a38d-0733dd17cf2a' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 20:07:14
	System	19 Aug 2020 20:07:14



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:07:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3932cc20-2cd9-4f57-a38d-0733dd17cf2a' User entered '19 Aug 2020 15:07'	(b) (4), (b) (6) System	19 Aug 2020 20:07:14
	System	19 Aug 2020 20:07:14

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Aug 2020 14:52'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Aug 2020 17:22'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '2a480156-26fd-4603-8628-27d19b8436e0' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Aug 2020 23:26:28
	System	19 Aug 2020 23:26:28

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:15', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '2a480156-26fd-4603-8628-27d19b8436e0' User entered '99.3'	(b) (4), (b) (6) System	19 Aug 2020 23:26:28
	System	19 Aug 2020 23:26:28

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:21', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '2a480156-26fd-4603-8628-27d19b8436e0' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 23:26:28
	System	19 Aug 2020 23:26:28

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:23', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '2a480156-26fd-4603-8628-27d19b8436e0' User entered '19 Aug 2020 18:26'	(b) (4), (b) (6) System	19 Aug 2020 23:26:28
	System	19 Aug 2020 23:26:28



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Aug 2020 18:17'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 2'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:53:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:08:46', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '52890e6a-b68e-4ec6-a18a-fddc61e48075' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Aug 2020 17:08:59
	System	20 Aug 2020 17:08:59

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:08:51', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '52890e6a-b68e-4ec6-a18a-fddc61e48075' User entered '98.4'	(b) (4), (b) (6) System	20 Aug 2020 17:08:59
	System	20 Aug 2020 17:08:59

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:08:53', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '52890e6a-b68e-4ec6-a18a-fddc61e48075'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 17:08:59

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:08:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '52890e6a-b68e-4ec6-a18a-fddc61e48075' User entered '20 Aug 2020 12:08'	(b) (4), (b) (6) System	20 Aug 2020 17:08:59
	System	20 Aug 2020 17:08:59

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 3'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:00:56', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '33f946f8-2377-4408-9111-3f3af2101334' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 17:01:10
	System	21 Aug 2020 17:01:10

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '33f946f8-2377-4408-9111-3f3af2101334' User entered '97.9'	(b) (4), (b) (6) System	21 Aug 2020 17:01:10
	System	21 Aug 2020 17:01:10

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:02', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '33f946f8-2377-4408-9111-3f3af2101334'	(b) (4), (b) (6)	
	System	21 Aug 2020 17:01:10
User entered 'No (N)'	System	21 Aug 2020 17:01:10

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:04', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '33f946f8-2377-4408-9111-3f3af2101334' User entered '21 Aug 2020 12:01'	(b) (4), (b) (6) System	21 Aug 2020 17:01:10
	System	21 Aug 2020 17:01:10

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25



US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 4'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:48:11', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '29254597-32c9-4dc7-94aa-036a648a414a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 21:48:34
	System	22 Aug 2020 21:48:34

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:48:16', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '29254597-32c9-4dc7-94aa-036a648a414a' User entered '98.9'	(b) (4), (b) (6) System	22 Aug 2020 21:48:34
	System	22 Aug 2020 21:48:34

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:48:29', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '29254597-32c9-4dc7-94aa-036a648a414a'	(b) (4), (b) (6)	
User entered 'No (N)'	System	22 Aug 2020 21:48:34

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:48:32', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '29254597-32c9-4dc7-94aa-036a648a414a' User entered '22 Aug 2020 16:48'	(b) (4), (b) (6) System	22 Aug 2020 21:48:34
	System	22 Aug 2020 21:48:34

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 5'	System	19 Aug 2020 19:38:25



US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:53:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8c028c19-0ca8-4cde-b6f6-84054b437a30' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:18
	System	23 Aug 2020 17:46:18

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:13', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8c028c19-0ca8-4cde-b6f6-84054b437a30' User entered '98.7'	(b) (4), (b) (6) System	23 Aug 2020 17:46:18
	System	23 Aug 2020 17:46:18

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:15', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8c028c19-0ca8-4cde-b6f6-84054b437a30'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Aug 2020 17:46:18

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:17', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8c028c19-0ca8-4cde-b6f6-84054b437a30' User entered '23 Aug 2020 12:46'	(b) (4), (b) (6) System	23 Aug 2020 17:46:18
	System	23 Aug 2020 17:46:18

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 6'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:53:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:00:31', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8972127b-ab79-4849-8bd5-64d31d6ea2c1' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Aug 2020 17:00:45
	System	24 Aug 2020 17:00:45



US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:00:37', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8972127b-ab79-4849-8bd5-64d31d6ea2c1' User entered '98.5'	(b) (4), (b) (6) System	24 Aug 2020 17:00:45
	System	24 Aug 2020 17:00:45

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:00:39', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8972127b-ab79-4849-8bd5-64d31d6ea2c1'	(b) (4), (b) (6)	
User entered 'No (N)'	System	24 Aug 2020 17:00:45

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:00:42', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8972127b-ab79-4849-8bd5-64d31d6ea2c1' User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 17:00:45
	System	24 Aug 2020 17:00:45

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 7'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:29', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e24192db-2b07-4acc-b58b-6839173ac5bd' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Aug 2020 17:00:38
	System	25 Aug 2020 17:00:38

US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:31', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e24192db-2b07-4acc-b58b-6839173ac5bd' User entered '98.0'	(b) (4), (b) (6) System	25 Aug 2020 17:00:38
	System	25 Aug 2020 17:00:38



US3042241

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:34', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e24192db-2b07-4acc-b58b-6839173ac5bd' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 17:00:38
	System	25 Aug 2020 17:00:38

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:35', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e24192db-2b07-4acc-b58b-6839173ac5bd' User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	25 Aug 2020 17:00:38
	System	25 Aug 2020 17:00:38

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:07:49', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '247a7025-9f4d-4de6-87d3-ee6b92e66a60'	(b) (4), (b) (6)	
User entered 'None (1)'	System	19 Aug 2020 20:52:16

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:51:53', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '247a7025-9f4d-4de6-87d3-ee6b92e66a60'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Aug 2020 20:52:16

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:52:06', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '247a7025-9f4d-4de6-87d3-ee6b92e66a60'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Aug 2020 20:52:16



US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:52:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '247a7025-9f4d-4de6-87d3-ee6b92e66a60'	(b) (4), (b) (6)	
User entered 'None (1)'	System	19 Aug 2020 20:52:16

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:52:14', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '247a7025-9f4d-4de6-87d3-eefb92e66a60' User entered '19 Aug 2020 15:52'	(b) (4), (b) (6) System	19 Aug 2020 20:52:16
	System	19 Aug 2020 20:52:16

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Aug 2020 14:52'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Aug 2020 17:22'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:27', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'd2b1fc3b-c5e3-4731-8045-924d6daa6e39' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 23:26:45
	System	19 Aug 2020 23:26:45

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:35', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'd2b1fc3b-c5e3-4731-8045-924d6daa6e39' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 23:26:45
	System	19 Aug 2020 23:26:45

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:38', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'd2b1fc3b-c5e3-4731-8045-924d6daa6e39' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 23:26:45
	System	19 Aug 2020 23:26:45



US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:40', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'd2b1fc3b-c5e3-4731-8045-924d6daa6e39' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 23:26:45
	System	19 Aug 2020 23:26:45

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:42', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'd2b1fc3b-c5e3-4731-8045-924d6daa6e39' User entered '19 Aug 2020 18:26'	(b) (4), (b) (6) System	19 Aug 2020 23:26:45
	System	19 Aug 2020 23:26:45

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Aug 2020 18:17'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 2'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:08:59', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4d50c365-bbab-4ba0-8d0b-210513949017'	(b) (4), (b) (6)	
User entered 'None (1)'	System	20 Aug 2020 17:09:13

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:02', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4d50c365-bbab-4ba0-8d0b-210513949017'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 17:09:13

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:04', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4d50c365-bbab-4ba0-8d0b-210513949017'	(b) (4), (b) (6)	
	System	20 Aug 2020 17:09:13
User entered 'No (N)'	System	20 Aug 2020 17:09:13



US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:08', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4d50c365-bbab-4ba0-8d0b-210513949017'	(b) (4), (b) (6)	
User entered 'None (1)'	System	20 Aug 2020 17:09:13

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4d50c365-bbab-4ba0-8d0b-210513949017' User entered '20 Aug 2020 12:09'	(b) (4), (b) (6) System	20 Aug 2020 17:09:13
	System	20 Aug 2020 17:09:13

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 3'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:39', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb946303-5bdf-43de-a256-a2e966aa7c34' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 17:01:51
	System	21 Aug 2020 17:01:51

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:41', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb946303-5bdf-43de-a256-a2e966aa7c34' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 17:01:51
	System	21 Aug 2020 17:01:51

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb946303-5bdf-43de-a256-a2e966aa7c34' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 17:01:51
	System	21 Aug 2020 17:01:51



US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:45', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb946303-5bdf-43de-a256-a2e966aa7c34' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 17:01:51
	System	21 Aug 2020 17:01:51

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:47', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb946303-5bdf-43de-a256-a2e966aa7c34' User entered '21 Aug 2020 12:01'	(b) (4), (b) (6) System	21 Aug 2020 17:01:51
	System	21 Aug 2020 17:01:51

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 4'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:02', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'fa587a7d-70a5-45af-8ddc-bb8c1ccb88b2'	(b) (4), (b) (6)	
	System	22 Aug 2020 21:49:30
User entered 'None (1)'	System	22 Aug 2020 21:49:30

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:04', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'fa587a7d-70a5-45af-8ddc-bb8c1ccb88b2'	(b) (4), (b) (6)	
	System	22 Aug 2020 21:49:30
User entered 'No (N)'	System	22 Aug 2020 21:49:30

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:17', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'fa587a7d-70a5-45af-8ddc-bb8c1ccb88b2'	(b) (4), (b) (6) System	22 Aug 2020 21:49:30
User entered 'No (N)'	System	22 Aug 2020 21:49:30



US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:25', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'fa587a7d-70a5-45af-8ddc-bb8c1ccb88b2'	(b) (4), (b) (6)	22 Aug 2020 21:49:30
User entered 'None (1)'	System	22 Aug 2020 21:49:30

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'fa587a7d-70a5-45af-8ddc-bb8c1ccb88b2'	(b) (4), (b) (6) System	22 Aug 2020 21:49:30
User entered '22 Aug 2020 16:49'	System	22 Aug 2020 21:49:30

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 5'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:20', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb7dfa7f-534c-4223-85d2-127f9cf8196d'	(b) (4), (b) (6)	
User entered 'None (1)'	System	23 Aug 2020 17:46:34

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb7dfa7f-534c-4223-85d2-127f9cf8196d' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:34
	System	23 Aug 2020 17:46:34

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:28', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb7dfa7f-534c-4223-85d2-127f9cf8196d' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:34
	System	23 Aug 2020 17:46:34



US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:30', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb7dfa7f-534c-4223-85d2-127f9cf8196d' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:34
	System	23 Aug 2020 17:46:34

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:32', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb7dfa7f-534c-4223-85d2-127f9cf8196d' User entered '23 Aug 2020 12:46'	(b) (4), (b) (6) System	23 Aug 2020 17:46:34
	System	23 Aug 2020 17:46:34

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 6'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:00:45', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6508d9b5-5023-466a-99ff-549d256561ef' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 17:00:59
	System	24 Aug 2020 17:00:59

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:00:47', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6508d9b5-5023-466a-99ff-549d256561ef' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 17:00:59
	System	24 Aug 2020 17:00:59

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:00:49', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6508d9b5-5023-466a-99ff-549d256561ef' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 17:00:59
	System	24 Aug 2020 17:00:59



US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:00:51', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6508d9b5-5023-466a-99ff-549d256561ef' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 17:00:59
	System	24 Aug 2020 17:00:59

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:00:53', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6508d9b5-5023-466a-99ff-549d256561ef' User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 17:00:59
	System	24 Aug 2020 17:00:59

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 7'	System	19 Aug 2020 19:38:25

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:39', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '47359308-78b6-4c34-96d4-bf06b341c396'	(b) (4), (b) (6)	
User entered 'None (1)'	System	25 Aug 2020 17:00:53

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:41', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '47359308-78b6-4c34-96d4-bf06b341c396'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Aug 2020 17:00:53

US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '47359308-78b6-4c34-96d4-bf06b341c396'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Aug 2020 17:00:53



US3042241

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:45', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '47359308-78b6-4c34-96d4-bf06b341c396'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:00:53
User entered 'None (1)'	System	25 Aug 2020 17:00:53

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:47', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '47359308-78b6-4c34-96d4-bf06b341c396'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:00:53
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:53

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:08:21', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '0deb39bd-9199-439b-8367-47e944d76d6c' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 20:08:44
	System	19 Aug 2020 20:08:44

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:08:24', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '0deb39bd-9199-439b-8367-47e944d76d6c' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 20:08:44
	System	19 Aug 2020 20:08:44

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:08:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '0deb39bd-9199-439b-8367-47e944d76d6c' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 20:08:44
	System	19 Aug 2020 20:08:44



US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:08:28', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '0deb39bd-9199-439b-8367-47e944d76d6c' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 20:08:44
	System	19 Aug 2020 20:08:44

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:08:30', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '0deb39bd-9199-439b-8367-47e944d76d6c' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 20:08:44
	System	19 Aug 2020 20:08:44

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:08:32', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '0deb39bd-9199-439b-8367-47e944d76d6c' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 20:08:44
	System	19 Aug 2020 20:08:44

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:08:37', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '0deb39bd-9199-439b-8367-47e944d76d6c'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Aug 2020 20:08:44

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T15:08:39', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '0deb39bd-9199-439b-8367-47e944d76d6c' User entered '19 Aug 2020 15:08'	(b) (4), (b) (6) System	19 Aug 2020 20:08:44
	System	19 Aug 2020 20:08:44

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Aug 2020 14:52'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Aug 2020 17:22'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 19:38:25



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:47', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '61cc6b8f-221c-4709-8291-41a2a42e8d44' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 23:27:08
	System	19 Aug 2020 23:27:08

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:52', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '61cc6b8f-221c-4709-8291-41a2a42e8d44' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 23:27:08
	System	19 Aug 2020 23:27:08

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '61cc6b8f-221c-4709-8291-41a2a42e8d44' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 23:27:08
	System	19 Aug 2020 23:27:08

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:57', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '61cc6b8f-221c-4709-8291-41a2a42e8d44' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 23:27:08
	System	19 Aug 2020 23:27:08

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:26:59', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '61cc6b8f-221c-4709-8291-41a2a42e8d44' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 23:27:08
	System	19 Aug 2020 23:27:08

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:27:01', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '61cc6b8f-221c-4709-8291-41a2a42e8d44' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 23:27:08
	System	19 Aug 2020 23:27:08

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:27:03', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '61cc6b8f-221c-4709-8291-41a2a42e8d44'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Aug 2020 23:27:08

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-19T18:27:05', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '61cc6b8f-221c-4709-8291-41a2a42e8d44'	(b) (4), (b) (6)	
User entered '19 Aug 2020 18:27'	System	19 Aug 2020 23:27:08



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Aug 2020 18:17'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 2'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:13', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'bd2c7b29-bf8e-491a-958c-c849bc44b9b9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:09:27
	System	20 Aug 2020 17:09:27

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:14', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'bd2c7b29-bf8e-491a-958c-c849bc44b9b9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:09:27
	System	20 Aug 2020 17:09:27

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:16', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'bd2c7b29-bf8e-491a-958c-c849bc44b9b9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:09:27
	System	20 Aug 2020 17:09:27

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:17', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'bd2c7b29-bf8e-491a-958c-c849bc44b9b9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:09:27
	System	20 Aug 2020 17:09:27

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:19', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'bd2c7b29-bf8e-491a-958c-c849bc44b9b9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:09:27
	System	20 Aug 2020 17:09:27



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:20', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'bd2c7b29-bf8e-491a-958c-c849bc44b9b9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 17:09:27
	System	20 Aug 2020 17:09:27

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:24', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'bd2c7b29-bf8e-491a-958c-c849bc44b9b9'	(b) (4), (b) (6)	
	System	20 Aug 2020 17:09:27
User entered 'No (N)'	System	20 Aug 2020 17:09:27

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-20T12:09:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'bd2c7b29-bf8e-491a-958c-c849bc44b9b9' User entered '20 Aug 2020 12:09'	(b) (4), (b) (6) System	20 Aug 2020 17:09:27
	System	20 Aug 2020 17:09:27

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 3'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:52', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '65930c74-4fea-48f4-b3d5-8e9ecc5cdda8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 17:02:28
	System	21 Aug 2020 17:02:28

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:53:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:01:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '65930c74-4fea-48f4-b3d5-8e9ecc5cdda8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 17:02:28
	System	21 Aug 2020 17:02:28



US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:02:06', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '65930c74-4fea-48f4-b3d5-8e9ecc5cdda8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 17:02:28
	System	21 Aug 2020 17:02:28

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:53:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:02:11', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '65930c74-4fea-48f4-b3d5-8e9ecc5cdda8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 17:02:28
	System	21 Aug 2020 17:02:28

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:02:12', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '65930c74-4fea-48f4-b3d5-8e9ecc5cdda8' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 17:02:28
	System	21 Aug 2020 17:02:28

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:02:16', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '65930c74-4fea-48f4-b3d5-8e9ecc5cdda8'	(b) (4), (b) (6)	
	System	21 Aug 2020 17:02:28
User entered 'No interference with activity (1)'	System	21 Aug 2020 17:02:28

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:02:21', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '65930c74-4fea-48f4-b3d5-8e9ecc5cdda8'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Aug 2020 17:02:28

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-21T12:02:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '65930c74-4fea-48f4-b3d5-8e9ecc5cdda8' User entered '21 Aug 2020 12:02'	(b) (4), (b) (6) System	21 Aug 2020 17:02:28
	System	21 Aug 2020 17:02:28

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 4'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:30', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '904100e0-3740-4997-8f6d-d6cda6359076' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 21:49:56
	System	22 Aug 2020 21:49:56

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:36', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '904100e0-3740-4997-8f6d-d6cda6359076' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 21:49:56
	System	22 Aug 2020 21:49:56

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:39', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '904100e0-3740-4997-8f6d-d6cda6359076' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 21:49:56
	System	22 Aug 2020 21:49:56

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:53:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:42', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '904100e0-3740-4997-8f6d-d6cda6359076' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 21:49:56
	System	22 Aug 2020 21:49:56

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:44', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '904100e0-3740-4997-8f6d-d6cda6359076' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 21:49:56
	System	22 Aug 2020 21:49:56

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:48', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '904100e0-3740-4997-8f6d-d6cda6359076' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 21:49:56
	System	22 Aug 2020 21:49:56

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:52', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '904100e0-3740-4997-8f6d-d6cda6359076' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 21:49:56
	System	22 Aug 2020 21:49:56



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-22T16:49:54', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '904100e0-3740-4997-8f6d-d6cda6359076' User entered '22 Aug 2020 16:49'	(b) (4), (b) (6) System	22 Aug 2020 21:49:56
	System	22 Aug 2020 21:49:56

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 5'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:36', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '710f4105-ab60-4c26-9f22-71a8ca5520ad' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:54
	System	23 Aug 2020 17:46:54

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:38', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '710f4105-ab60-4c26-9f22-71a8ca5520ad' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:54
	System	23 Aug 2020 17:46:54

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:40', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '710f4105-ab60-4c26-9f22-71a8ca5520ad' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:54
	System	23 Aug 2020 17:46:54

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:53:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:42', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '710f4105-ab60-4c26-9f22-71a8ca5520ad' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:54
	System	23 Aug 2020 17:46:54



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:44', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '710f4105-ab60-4c26-9f22-71a8ca5520ad' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:54
	System	23 Aug 2020 17:46:54

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:48', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '710f4105-ab60-4c26-9f22-71a8ca5520ad' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:54
	System	23 Aug 2020 17:46:54

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:52', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '710f4105-ab60-4c26-9f22-71a8ca5520ad' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 17:46:54
	System	23 Aug 2020 17:46:54

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-23T12:46:53', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '710f4105-ab60-4c26-9f22-71a8ca5520ad' User entered '23 Aug 2020 12:46'	(b) (4), (b) (6) System	23 Aug 2020 17:46:54
	System	23 Aug 2020 17:46:54

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 6'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:01:02', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8ded9e48-4db1-4f6c-8e37-75fee1fe59c5' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 17:02:06
	System	24 Aug 2020 17:02:06



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:01:06', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8ded9e48-4db1-4f6c-8e37-75fee1fe59c5' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 17:02:06
	System	24 Aug 2020 17:02:06

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:01:08', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8ded9e48-4db1-4f6c-8e37-75fee1fe59c5' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 17:02:06
	System	24 Aug 2020 17:02:06

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:01:13', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8ded9e48-4db1-4f6c-8e37-75fee1fe59c5' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 17:02:06
	System	24 Aug 2020 17:02:06

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:01:35', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8ded9e48-4db1-4f6c-8e37-75fee1fe59c5'	(b) (4), (b) (6)	
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Aug 2020 17:02:06

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:01:44', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8ded9e48-4db1-4f6c-8e37-75fee1fe59c5'	(b) (4), (b) (6)	
	System	24 Aug 2020 17:02:06
User entered 'No interference with activity (1)'	System	24 Aug 2020 17:02:06

US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:01:51', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8ded9e48-4db1-4f6c-8e37-75fee1fe59c5' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 17:02:06
	System	24 Aug 2020 17:02:06

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-24T12:01:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8ded9e48-4db1-4f6c-8e37-75fee1fe59c5' User entered '24 Aug 2020 12:01'	(b) (4), (b) (6) System	24 Aug 2020 17:02:06
	System	24 Aug 2020 17:02:06

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25



**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 7'	System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:50', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dbd968b1-0cbb-47a7-8b82-0c6b586ba9c6' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 17:01:15
	System	25 Aug 2020 17:01:15

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:52', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dbd968b1-0cbb-47a7-8b82-0c6b586ba9c6' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 17:01:15
	System	25 Aug 2020 17:01:15

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:53', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dbd968b1-0cbb-47a7-8b82-0c6b586ba9c6' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 17:01:15
	System	25 Aug 2020 17:01:15

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dbd968b1-0cbb-47a7-8b82-0c6b586ba9c6' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 17:01:15
	System	25 Aug 2020 17:01:15

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:56', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dbd968b1-0cbb-47a7-8b82-0c6b586ba9c6' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 17:01:15
	System	25 Aug 2020 17:01:15

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:00:58', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dbd968b1-0cbb-47a7-8b82-0c6b586ba9c6' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 17:01:15
	System	25 Aug 2020 17:01:15



US3042241

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:01:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dbd968b1-0cbb-47a7-8b82-0c6b586ba9c6'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Aug 2020 17:01:15

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-08-25T12:01:02', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dbd968b1-0cbb-47a7-8b82-0c6b586ba9c6' User entered '25 Aug 2020 12:01'	(b) (4), (b) (6) System	25 Aug 2020 17:01:15
	System	25 Aug 2020 17:01:15

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	19 Aug 2020 19:38:25

**US3042241**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	26 Aug 2020 16:24:15

**US3042241**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered '26 Aug 2020'	Rylea Gulick (b) (4)	26 Aug 2020 16:24:15

**US3042241**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4)	26 Aug 2020 16:24:15

**US3042241**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered empty.	Rylea Gulick (b) (4)	26 Aug 2020 16:24:15



**US3042241**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4)	26 Aug 2020 16:24:17

**US3042241**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:14
User entered 'I'	System	26 Aug 2020 16:24:17

**US3042241**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:16:37

**US3042241**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 15:41:37
User entered '02 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:16:37

**US3042241**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:16:37

**US3042241**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:16:37

**US3042241**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:16:39

**US3042241**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User entered '1'	(b) (4), (b) (6) System	03 Sep 2020 17:16:39



**US3042241**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:37:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	09 Sep 2020 23:12:36
	(b) (4)	

**US3042241**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:37:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '09 Sep 2020'	Rylea Gulick (b) (4)	09 Sep 2020 23:12:36
	(b) (4)	

**US3042241**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:37:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	09 Sep 2020 23:12:36
	(b) (4)	

**US3042241**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:37:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	09 Sep 2020 23:12:36
	(b) (4)	

**US3042241**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:37:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	09 Sep 2020 23:12:37
	(b) (4)	

**US3042241**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:37:03
User entered 'I'	(b) (4), (b) (6) System	09 Sep 2020 23:12:37

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Sep 2020 21:12:42
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '16 Sep 2020'	Rylea Gulick (b) (4)	16 Sep 2020 21:12:42
	(b) (4)	



**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	16 Sep 2020 21:12:42
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'VISIT2'	(b) (4), (b) (6) System	16 Sep 2020 21:12:42

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '16 Sep 2020'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '11:15'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered '16 Sep 2020 11:15'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '37.2' C	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	



**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '91'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'bpm'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '12'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '112'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54



US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '84'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:53:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '16 Sep 2020'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '12:35'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered '16 Sep 2020 12:35'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '37.3' C	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	



**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '90'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'bpm'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '12'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '111'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54



US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '82'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:54
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:53:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'mmHg'	(b) (4), (b) (6) System	16 Sep 2020 21:14:54

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:58
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '16 Sep 2020'	Rylea Gulick (b) (4)	16 Sep 2020 21:14:58
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:03
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '16 Sep 2020'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:03
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Urine (URINE)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:03
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:03
	(b) (4)	



**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:03
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Sep 2020 21:15:03
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Sep 2020 21:15:03
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered empty.	(b) (4), (b) (6) System	16 Sep 2020 21:15:03

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:53:57**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Sep 2020 17:03:19
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Sep 2020 17:03:19
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

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)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Sep 2020 17:03:19
	(b) (4)	

US3042241

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '16 Sep 2020'	Rylea Gulick (b) (4)	16 Sep 2020 17:03:19
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '12:00'	Rylea Gulick (b) (4)	16 Sep 2020 17:03:19
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:53:57**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

US3042241

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4)	16 Sep 2020 17:03:19
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:53:57**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'ONCE'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

US3042241

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:53:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:14
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '16 Sep 2020'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:14
	(b) (4)	



**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '11:37'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:14
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered '16 Sep 2020 11:37'	(b) (4), (b) (6) System	16 Sep 2020 21:15:14

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:53:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '16 Sep 2020'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:21
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:21
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:21
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:53:57**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '11:30'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:21
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered '16 Sep 2020 11:30'	(b) (4), (b) (6) System	16 Sep 2020 21:15:21

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:21
	(b) (4)	



**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:21
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:53:57**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Sep 2020 21:15:21
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered empty.	(b) (4), (b) (6) System	16 Sep 2020 21:15:21

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Sep 2020 21:15:24
	(b) (4)	

**US3042241**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(167630 Apr 2021 05:10:52
User entered '1'	(b) (4), (b) (6) System	16 Sep 2020 21:15:24

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:32:24', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '70ef0a68-8cfd-4d26-ba1d-26077f7b873c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Sep 2020 17:32:53
	System	16 Sep 2020 17:32:53

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:32:27', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '70ef0a68-8cfd-4d26-ba1d-26077f7b873c' User entered '99.1'	(b) (4), (b) (6) System	16 Sep 2020 17:32:53
	System	16 Sep 2020 17:32:53



US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:32:45', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '70ef0a68-8cfd-4d26-ba1d-26077f7b873c'	(b) (4), (b) (6)	
	System	16 Sep 2020 17:32:53
User entered 'No (N)'	System	16 Sep 2020 17:32:53

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:32:50', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '70ef0a68-8cfd-4d26-ba1d-26077f7b873c' User entered '16 Sep 2020 12:32'	(b) (4), (b) (6) System	16 Sep 2020 17:32:53
	System	16 Sep 2020 17:32:53

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '16 Sep 2020 12:20'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '16 Sep 2020 14:50'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:04:21', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '94b96065-32c9-476a-ae52-5b2c4f33ce99'	(b) (4), (b) (6)	
	System	16 Sep 2020 23:04:31
User entered 'Yes (Y)'	System	16 Sep 2020 23:04:31

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:04:24', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '94b96065-32c9-476a-ae52-5b2c4f33ce99' User entered '98.4'	(b) (4), (b) (6) System	16 Sep 2020 23:04:31
	System	16 Sep 2020 23:04:31

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:04:27', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '94b96065-32c9-476a-ae52-5b2c4f33ce99'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Sep 2020 23:04:31



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:04:29', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '94b96065-32c9-476a-ae52-5b2c4f33ce99'	(b) (4), (b) (6) System	16 Sep 2020 23:04:31
User entered '16 Sep 2020 18:04'	System	16 Sep 2020 23:04:31

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '16 Sep 2020 15:45'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 2'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:09', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb40e8e0-75a1-4c6f-aad5-62f894f7efdd' User entered 'Yes (Y)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:12
	System	17 Sep 2020 17:02:12

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:13', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb40e8e0-75a1-4c6f-aad5-62f894f7efdd' User entered '97.6'	(b) (4), (b) (6) System	17 Sep 2020 17:02:12
	System	17 Sep 2020 17:02:12

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:15', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb40e8e0-75a1-4c6f-aad5-62f894f7efdd' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:12
	System	17 Sep 2020 17:02:12

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:17', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'eb40e8e0-75a1-4c6f-aad5-62f894f7efdd' User entered '17 Sep 2020 12:01'	(b) (4), (b) (6) System	17 Sep 2020 17:02:12
	System	17 Sep 2020 17:02:12



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 3'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:23:50', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8d02b725-459b-481d-8c48-3af1f6d5e45f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:12
	System	18 Sep 2020 18:24:12

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:05', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8d02b725-459b-481d-8c48-3af1f6d5e45f' User entered '98.4'	(b) (4), (b) (6) System	18 Sep 2020 18:24:12
	System	18 Sep 2020 18:24:12

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:08', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8d02b725-459b-481d-8c48-3af1f6d5e45f' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:12
	System	18 Sep 2020 18:24:12

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '8d02b725-459b-481d-8c48-3af1f6d5e45f' User entered '18 Sep 2020 13:24'	(b) (4), (b) (6) System	18 Sep 2020 18:24:12
	System	18 Sep 2020 18:24:12

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 4'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:43:44', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '68096802-51c3-41c8-a568-137a3204ec3d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Sep 2020 17:44:04
	System	19 Sep 2020 17:44:04

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:43:48', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '68096802-51c3-41c8-a568-137a3204ec3d' User entered '98.1'	(b) (4), (b) (6) System	19 Sep 2020 17:44:04
	System	19 Sep 2020 17:44:04

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:43:51', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '68096802-51c3-41c8-a568-137a3204ec3d' User entered 'No (N)'	(b) (4), (b) (6) System	19 Sep 2020 17:44:04
	System	19 Sep 2020 17:44:04

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:01', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '68096802-51c3-41c8-a568-137a3204ec3d' User entered '19 Sep 2020 12:44'	(b) (4), (b) (6) System	19 Sep 2020 17:44:04
	System	19 Sep 2020 17:44:04

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 5'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:13:28', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1cecf94-a703-4306-be94-3005d9194fc1' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:08
	System	21 Sep 2020 01:14:08

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:13:31', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1cecf94-a703-4306-be94-3005d9194fc1' User entered '98.6'	(b) (4), (b) (6) System	21 Sep 2020 01:14:08
	System	21 Sep 2020 01:14:08

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:13:38', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1cecf94-a703-4306-be94-3005d9194fc1' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:08
	System	21 Sep 2020 01:14:08

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:13:51', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1cecf94-a703-4306-be94-3005d9194fc1' User entered '20 Sep 2020 20:13'	(b) (4), (b) (6) System	21 Sep 2020 01:14:08
	System	21 Sep 2020 01:14:08

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 6'	System	16 Sep 2020 17:03:19



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:02:50', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e7e4f70b-e49e-4839-acce-c7ed9373ed77' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:03
	System	21 Sep 2020 17:06:03

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:02:54', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e7e4f70b-e49e-4839-acce-c7ed9373ed77' User entered '98.9'	(b) (4), (b) (6) System	21 Sep 2020 17:06:03
	System	21 Sep 2020 17:06:03

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:02:56', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e7e4f70b-e49e-4839-acce-c7ed9373ed77'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:06:03
User entered 'No (N)'	System	21 Sep 2020 17:06:03

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:02:58', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e7e4f70b-e49e-4839-acce-c7ed9373ed77' User entered '21 Sep 2020 12:02'	(b) (4), (b) (6) System	21 Sep 2020 17:06:03
	System	21 Sep 2020 17:06:03

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 7'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:01:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9d43671d-56a9-41e9-aa48-b701b8eb56bc' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:03
	System	22 Sep 2020 17:04:03



US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:53:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:01:58', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9d43671d-56a9-41e9-aa48-b701b8eb56bc' User entered '98.6'	(b) (4), (b) (6) System	22 Sep 2020 17:04:03
	System	22 Sep 2020 17:04:03

US3042241

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9d43671d-56a9-41e9-aa48-b701b8eb56bc' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:03
	System	22 Sep 2020 17:04:03

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:03', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9d43671d-56a9-41e9-aa48-b701b8eb56bc' User entered '22 Sep 2020 12:02'	(b) (4), (b) (6) System	22 Sep 2020 17:04:03
	System	22 Sep 2020 17:04:03

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:32:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dd94f105-bf9e-4ae9-9bcb-77d058b9a692'	(b) (4), (b) (6)	
	System	16 Sep 2020 17:33:14
User entered 'None (1)'	System	16 Sep 2020 17:33:14

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:32:57', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dd94f105-bf9e-4ae9-9bcb-77d058b9a692'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Sep 2020 17:33:14



US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dd94f105-bf9e-4ae9-9bcb-77d058b9a692'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Sep 2020 17:33:14

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:03', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dd94f105-bf9e-4ae9-9bcb-77d058b9a692'	(b) (4), (b) (6)	
	System	16 Sep 2020 17:33:14
User entered 'None (1)'	System	16 Sep 2020 17:33:14

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:12', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'dd94f105-bf9e-4ae9-9bcb-77d058b9a692'	(b) (4), (b) (6)	
	System	16 Sep 2020 17:33:14
User entered '16 Sep 2020 12:33'	System	16 Sep 2020 17:33:14

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '16 Sep 2020 12:20'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '16 Sep 2020 14:50'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:17', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'daef427e-098b-4cf9-92a2-20f782162f54'	(b) (4), (b) (6)	
	System	16 Sep 2020 23:05:37
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 23:05:37

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:19', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'daef427e-098b-4cf9-92a2-20f782162f54' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 23:05:37
	System	16 Sep 2020 23:05:37



US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:22', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'daef427e-098b-4cf9-92a2-20f782162f54' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 23:05:37
	System	16 Sep 2020 23:05:37

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:29', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'daef427e-098b-4cf9-92a2-20f782162f54' User entered 'None (1)'	(b) (4), (b) (6) System	16 Sep 2020 23:05:37
	System	16 Sep 2020 23:05:37

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:31', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'daef427e-098b-4cf9-92a2-20f782162f54' User entered '16 Sep 2020 18:05'	(b) (4), (b) (6) System	16 Sep 2020 23:05:37
	System	16 Sep 2020 23:05:37

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '16 Sep 2020 15:45'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 2'	System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:23', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '574025ac-4e60-4053-91d1-be27a7a7fc8f' User entered 'None (1)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:27
	System	17 Sep 2020 17:02:27

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '574025ac-4e60-4053-91d1-be27a7a7fc8f' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:27
	System	17 Sep 2020 17:02:27



US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:28', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '574025ac-4e60-4053-91d1-be27a7a7fc8f' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:27
	System	17 Sep 2020 17:02:27

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:30', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '574025ac-4e60-4053-91d1-be27a7a7fc8f' User entered 'None (1)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:27
	System	17 Sep 2020 17:02:27

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:31', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '574025ac-4e60-4053-91d1-be27a7a7fc8f' User entered '17 Sep 2020 12:01'	(b) (4), (b) (6) System	17 Sep 2020 17:02:27
	System	17 Sep 2020 17:02:27

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 3'	System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:14', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a92fd87f-96e3-4d1f-ace0-d31986df83ba' User entered 'None (1)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:26
	System	18 Sep 2020 18:24:26

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:18', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a92fd87f-96e3-4d1f-ace0-d31986df83ba' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:26
	System	18 Sep 2020 18:24:26



US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:20', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a92fd87f-96e3-4d1f-ace0-d31986df83ba' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:26
	System	18 Sep 2020 18:24:26

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:22', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a92fd87f-96e3-4d1f-ace0-d31986df83ba' User entered 'None (1)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:26
	System	18 Sep 2020 18:24:26

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:25', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a92fd87f-96e3-4d1f-ace0-d31986df83ba' User entered '18 Sep 2020 13:24'	(b) (4), (b) (6) System	18 Sep 2020 18:24:26
	System	18 Sep 2020 18:24:26

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 4'	System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:04', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '5d42c78e-0a88-4f6b-9245-f84a6eafd50d'	(b) (4), (b) (6)	
	System	19 Sep 2020 17:44:29
User entered 'None (1)'	System	19 Sep 2020 17:44:29

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:21', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '5d42c78e-0a88-4f6b-9245-f84a6eafd50d' User entered 'No (N)'	(b) (4), (b) (6) System	19 Sep 2020 17:44:29
	System	19 Sep 2020 17:44:29



US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:23', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '5d42c78e-0a88-4f6b-9245-f84a6eafd50d' User entered 'No (N)'	(b) (4), (b) (6) System	19 Sep 2020 17:44:29
	System	19 Sep 2020 17:44:29

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:24', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '5d42c78e-0a88-4f6b-9245-f84a6eafd50d'	(b) (4), (b) (6)	
	System	19 Sep 2020 17:44:29
User entered 'None (1)'	System	19 Sep 2020 17:44:29

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:27', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '5d42c78e-0a88-4f6b-9245-f84a6eafd50d' User entered '19 Sep 2020 12:44'	(b) (4), (b) (6) System	19 Sep 2020 17:44:29
	System	19 Sep 2020 17:44:29

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 5'	System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:03', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '98359ba0-8e39-4913-a11d-95fc26c731fd' User entered 'None (1)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:18
	System	21 Sep 2020 01:14:18

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:07', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '98359ba0-8e39-4913-a11d-95fc26c731fd' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:18
	System	21 Sep 2020 01:14:18



US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:08', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '98359ba0-8e39-4913-a11d-95fc26c731fd' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:18
	System	21 Sep 2020 01:14:18

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '98359ba0-8e39-4913-a11d-95fc26c731fd' User entered 'None (1)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:18
	System	21 Sep 2020 01:14:18

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:13', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '98359ba0-8e39-4913-a11d-95fc26c731fd' User entered '20 Sep 2020 20:14'	(b) (4), (b) (6) System	21 Sep 2020 01:14:18
	System	21 Sep 2020 01:14:18

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 6'	System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '20556081-8de0-4973-8fd7-04db1e0b65c2'	(b) (4), (b) (6)	
User entered 'None (1)'	System	21 Sep 2020 17:06:17

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:02', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '20556081-8de0-4973-8fd7-04db1e0b65c2' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:17
	System	21 Sep 2020 17:06:17



US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:04', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '20556081-8de0-4973-8fd7-04db1e0b65c2' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:17
	System	21 Sep 2020 17:06:17

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:05', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '20556081-8de0-4973-8fd7-04db1e0b65c2'	(b) (4), (b) (6)	
User entered 'None (1)'	System	21 Sep 2020 17:06:17

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:08', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '20556081-8de0-4973-8fd7-04db1e0b65c2' User entered '21 Sep 2020 12:03'	(b) (4), (b) (6) System	21 Sep 2020 17:06:17
	System	21 Sep 2020 17:06:17

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 7'	System	16 Sep 2020 17:03:19

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:06', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4a97e1d4-4e4b-40a9-90c9-4dcde759c121' User entered 'None (1)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:36
	System	22 Sep 2020 17:04:36

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:08', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4a97e1d4-4e4b-40a9-90c9-4dcde759c121' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:36
	System	22 Sep 2020 17:04:36



US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4a97e1d4-4e4b-40a9-90c9-4dcde759c121' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:36
	System	22 Sep 2020 17:04:36

US3042241

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:12', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4a97e1d4-4e4b-40a9-90c9-4dcde759c121' User entered 'None (1)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:36
	System	22 Sep 2020 17:04:36

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:14', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '4a97e1d4-4e4b-40a9-90c9-4dcde759c121' User entered '22 Sep 2020 12:02'	(b) (4), (b) (6) System	22 Sep 2020 17:04:36
	System	22 Sep 2020 17:04:36

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:16', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6bfb9db5-db1a-44a0-80af-ca6dea518223' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 17:33:37
	System	16 Sep 2020 17:33:37

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:18', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6bfb9db5-db1a-44a0-80af-ca6dea518223' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 17:33:37
	System	16 Sep 2020 17:33:37



US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:20', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6bfb9db5-db1a-44a0-80af-ca6dea518223' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 17:33:37
	System	16 Sep 2020 17:33:37

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:22', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6bfb9db5-db1a-44a0-80af-ca6dea518223' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 17:33:37
	System	16 Sep 2020 17:33:37

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:24', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6bfb9db5-db1a-44a0-80af-ca6dea518223' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 17:33:37
	System	16 Sep 2020 17:33:37

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6bfb9db5-db1a-44a0-80af-ca6dea518223' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 17:33:37
	System	16 Sep 2020 17:33:37

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:31', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6bfb9db5-db1a-44a0-80af-ca6dea518223' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 17:33:37
	System	16 Sep 2020 17:33:37

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T12:33:35', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '6bfb9db5-db1a-44a0-80af-ca6dea518223' User entered '16 Sep 2020 12:33'	(b) (4), (b) (6) System	16 Sep 2020 17:33:37
	System	16 Sep 2020 17:33:37

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '16 Sep 2020 12:20'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '16 Sep 2020 14:50'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:37', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9980f184-84d4-4d71-8198-80aa02f23a18' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 23:06:22
	System	16 Sep 2020 23:06:22

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:39', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9980f184-84d4-4d71-8198-80aa02f23a18'	(b) (4), (b) (6)	
	System	16 Sep 2020 23:06:22
User entered 'No interference with activity (1)'	System	16 Sep 2020 23:06:22

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:42', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9980f184-84d4-4d71-8198-80aa02f23a18' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	16 Sep 2020 23:06:22
	System	16 Sep 2020 23:06:22

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:44', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9980f184-84d4-4d71-8198-80aa02f23a18' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 23:06:22
	System	16 Sep 2020 23:06:22

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:46', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9980f184-84d4-4d71-8198-80aa02f23a18' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 23:06:22
	System	16 Sep 2020 23:06:22

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:05:48', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9980f184-84d4-4d71-8198-80aa02f23a18'	(b) (4), (b) (6)	
	System	16 Sep 2020 23:06:22
User entered 'No interference with activity (1)'	System	16 Sep 2020 23:06:22

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:06:17', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9980f184-84d4-4d71-8198-80aa02f23a18' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 23:06:22
	System	16 Sep 2020 23:06:22



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-16T18:06:19', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9980f184-84d4-4d71-8198-80aa02f23a18' User entered '16 Sep 2020 18:06'	(b) (4), (b) (6) System	16 Sep 2020 23:06:22
	System	16 Sep 2020 23:06:22

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '16 Sep 2020 15:45'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 2'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:35', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '973dc986-c114-4a52-922e-e21490995807' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:49
	System	17 Sep 2020 17:02:49

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:36', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '973dc986-c114-4a52-922e-e21490995807' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:49
	System	17 Sep 2020 17:02:49

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:38', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '973dc986-c114-4a52-922e-e21490995807' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:49
	System	17 Sep 2020 17:02:49

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:39', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '973dc986-c114-4a52-922e-e21490995807' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:49
	System	17 Sep 2020 17:02:49



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:40', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '973dc986-c114-4a52-922e-e21490995807' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:49
	System	17 Sep 2020 17:02:49

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:42', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '973dc986-c114-4a52-922e-e21490995807' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:49
	System	17 Sep 2020 17:02:49

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:44', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '973dc986-c114-4a52-922e-e21490995807' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 17:02:49
	System	17 Sep 2020 17:02:49

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-17T12:01:48', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '973dc986-c114-4a52-922e-e21490995807' User entered '17 Sep 2020 12:01'	(b) (4), (b) (6) System	17 Sep 2020 17:02:49
	System	17 Sep 2020 17:02:49

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 3'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:28', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '17f7730c-719a-4a13-98db-0351e9adf489' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:53
	System	18 Sep 2020 18:24:53



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:29', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '17f7730c-719a-4a13-98db-0351e9adf489' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:53
	System	18 Sep 2020 18:24:53

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:33', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '17f7730c-719a-4a13-98db-0351e9adf489' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:53
	System	18 Sep 2020 18:24:53

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:35', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '17f7730c-719a-4a13-98db-0351e9adf489' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:53
	System	18 Sep 2020 18:24:53

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:36', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '17f7730c-719a-4a13-98db-0351e9adf489' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:53
	System	18 Sep 2020 18:24:53

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:39', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '17f7730c-719a-4a13-98db-0351e9adf489' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:53
	System	18 Sep 2020 18:24:53

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:46', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '17f7730c-719a-4a13-98db-0351e9adf489' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 18:24:53
	System	18 Sep 2020 18:24:53

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-18T13:24:50', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '17f7730c-719a-4a13-98db-0351e9adf489' User entered '18 Sep 2020 13:24'	(b) (4), (b) (6) System	18 Sep 2020 18:24:53
	System	18 Sep 2020 18:24:53

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 4'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:39', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3fcd0c7b-9d93-490e-becd-e089d236a9dd' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 17:45:01
	System	19 Sep 2020 17:45:01

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:41', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3fcd0c7b-9d93-490e-becd-e089d236a9dd' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 17:45:01
	System	19 Sep 2020 17:45:01

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:47', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3fcd0c7b-9d93-490e-becd-e089d236a9dd' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 17:45:01
	System	19 Sep 2020 17:45:01

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:49', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3fcd0c7b-9d93-490e-becd-e089d236a9dd' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 17:45:01
	System	19 Sep 2020 17:45:01

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:51', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3fcd0c7b-9d93-490e-becd-e089d236a9dd' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 17:45:01
	System	19 Sep 2020 17:45:01

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:52', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3fcd0c7b-9d93-490e-becd-e089d236a9dd' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 17:45:01
	System	19 Sep 2020 17:45:01



US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3fcd0c7b-9d93-490e-becd-e089d236a9dd' User entered 'No (N)'	(b) (4), (b) (6) System	19 Sep 2020 17:45:01
	System	19 Sep 2020 17:45:01

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-19T12:44:56', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '3fcd0c7b-9d93-490e-becd-e089d236a9dd' User entered '19 Sep 2020 12:44'	(b) (4), (b) (6) System	19 Sep 2020 17:45:01
	System	19 Sep 2020 17:45:01

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 5'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:22', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e59728d7-6e10-47c5-a558-ac1c120b3888' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:40
	System	21 Sep 2020 01:14:40

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:24', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e59728d7-6e10-47c5-a558-ac1c120b3888' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:40
	System	21 Sep 2020 01:14:40

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e59728d7-6e10-47c5-a558-ac1c120b3888' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:40
	System	21 Sep 2020 01:14:40



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:27', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e59728d7-6e10-47c5-a558-ac1c120b3888' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:40
	System	21 Sep 2020 01:14:40

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:29', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e59728d7-6e10-47c5-a558-ac1c120b3888' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:40
	System	21 Sep 2020 01:14:40

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:30', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e59728d7-6e10-47c5-a558-ac1c120b3888' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:40
	System	21 Sep 2020 01:14:40

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:32', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e59728d7-6e10-47c5-a558-ac1c120b3888' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 01:14:40
	System	21 Sep 2020 01:14:40

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-20T20:14:34', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e59728d7-6e10-47c5-a558-ac1c120b3888' User entered '20 Sep 2020 20:14'	(b) (4), (b) (6) System	21 Sep 2020 01:14:40
	System	21 Sep 2020 01:14:40

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 6'	System	16 Sep 2020 17:03:19



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:11', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1e16a782-9a86-42d7-8417-0714bcf99316' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:34
	System	21 Sep 2020 17:06:34

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:13', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1e16a782-9a86-42d7-8417-0714bcf99316' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:34
	System	21 Sep 2020 17:06:34

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:53:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:14', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1e16a782-9a86-42d7-8417-0714bcf99316' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:34
	System	21 Sep 2020 17:06:34

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:53:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:16', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1e16a782-9a86-42d7-8417-0714bcf99316' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:34
	System	21 Sep 2020 17:06:34

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:17', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1e16a782-9a86-42d7-8417-0714bcf99316' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:34
	System	21 Sep 2020 17:06:34

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:18', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1e16a782-9a86-42d7-8417-0714bcf99316' User entered 'None (0)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:34
	System	21 Sep 2020 17:06:34

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:20', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1e16a782-9a86-42d7-8417-0714bcf99316' User entered 'No (N)'	(b) (4), (b) (6) System	21 Sep 2020 17:06:34
	System	21 Sep 2020 17:06:34

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-21T12:03:22', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1e16a782-9a86-42d7-8417-0714bcf99316' User entered '21 Sep 2020 12:03'	(b) (4), (b) (6) System	21 Sep 2020 17:06:34
	System	21 Sep 2020 17:06:34



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '21 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	16 Sep 2020 17:03:19
User entered 'Day 7'	System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:16', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '79ed484f-4bff-4644-8e54-26be0c106be8' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:59
	System	22 Sep 2020 17:04:59

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:18', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '79ed484f-4bff-4644-8e54-26be0c106be8' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:59
	System	22 Sep 2020 17:04:59

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:19', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '79ed484f-4bff-4644-8e54-26be0c106be8' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:59
	System	22 Sep 2020 17:04:59

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:21', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '79ed484f-4bff-4644-8e54-26be0c106be8' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:59
	System	22 Sep 2020 17:04:59

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:22', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '79ed484f-4bff-4644-8e54-26be0c106be8' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:59
	System	22 Sep 2020 17:04:59



**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:23', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '79ed484f-4bff-4644-8e54-26be0c106be8' User entered 'None (0)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:59
	System	22 Sep 2020 17:04:59

US3042241

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:53:57

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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:25', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '79ed484f-4bff-4644-8e54-26be0c106be8' User entered 'No (N)'	(b) (4), (b) (6) System	22 Sep 2020 17:04:59
	System	22 Sep 2020 17:04:59

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-09-22T12:02:29', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '79ed484f-4bff-4644-8e54-26be0c106be8' User entered '22 Sep 2020 12:02'	(b) (4), (b) (6) System	22 Sep 2020 17:04:59
	System	22 Sep 2020 17:04:59

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:53:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	16 Sep 2020 17:03:19

**US3042241**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 13:27:37

**US3042241**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered '23 Sep 2020'	Rylea Gulick (b) (4)	24 Sep 2020 13:27:37

**US3042241**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4)	24 Sep 2020 13:27:37



**US3042241**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered empty.	Rylea Gulick (b) (4)	24 Sep 2020 13:27:37

**US3042241**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:14
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 13:27:39

**US3042241**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:06:14
User entered 'I'	System	24 Sep 2020 13:27:39

**US3042241**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:06:09
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	06 Oct 2020 15:12:25

**US3042241**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:06:09
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '30 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:12:25

**US3042241**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:06:09
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4)	06 Oct 2020 15:12:25

**US3042241**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:06:09
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	Rylea Gulick (b) (4)	06 Oct 2020 15:12:25

**US3042241**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:06:09
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:12:27



**US3042241**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:06:09
User entered 'I'	System	06 Oct 2020 15:12:27

**US3042241**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:57:51
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	07 Oct 2020 18:23:57
	(b) (4)	

**US3042241**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:57:51
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '07 Oct 2020'	Rylea Gulick (b) (4)	07 Oct 2020 18:23:57
	(b) (4)	

**US3042241**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:57:51
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	07 Oct 2020 18:23:57
	(b) (4)	

**US3042241**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:57:51
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	07 Oct 2020 18:23:57
	(b) (4)	

US3042241

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:53:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:57:51
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	07 Oct 2020 18:24:02
	(b) (4)	

**US3042241**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:57:51
User entered 'I'	System	07 Oct 2020 18:24:02

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:35:51



**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '14 Oct 2020'	Rylea Gulick (b) (4)	14 Oct 2020 14:35:51
	(b) (4)	

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[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 04:02:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:35:51

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User entered 'VISIT3'	(b) (4), (b) (6) System	14 Oct 2020 14:35:51

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Oct 2020 14:36:16
	(b) (4)	

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '14 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:36:16

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '09:05'	Rylea Gulick (b) (4)	14 Oct 2020 14:36:16
	(b) (4)	

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User entered '14 Oct 2020 09:05'	(b) (4), (b) (6) System	14 Oct 2020 14:36:16

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '36.9' C	Rylea Gulick (b) (4)	14 Oct 2020 14:36:16
	(b) (4)	



**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	14 Oct 2020 14:36:16
	(b) (4)	

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Oct 2020 14:36:16
	(b) (4)	

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '72'	Rylea Gulick (b) (4)	14 Oct 2020 14:36:16
	(b) (4)	

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User entered 'bpm'	(b) (4), (b) (6) System	14 Oct 2020 14:36:16

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:36:16

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User entered 'breaths/min'	(b) (4), (b) (6) System	14 Oct 2020 14:36:16

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '111'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:36:16

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User entered 'mmHg'	(b) (4), (b) (6) System	14 Oct 2020 14:36:16



**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '77'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:36:16

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User entered 'mmHg'	(b) (4), (b) (6) System	14 Oct 2020 14:36:16

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:11

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:11

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Oct 2020 14:36:20
	(b) (4)	

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '14 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:36:20

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:36:29

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '14 Oct 2020'	Rylea Gulick (b) (4)	14 Oct 2020 14:36:29
	(b) (4)	



**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered '09:01'	Rylea Gulick (b) (4)	14 Oct 2020 14:36:29
	(b) (4)	

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User entered '14 Oct 2020 09:01'	(b) (4), (b) (6) System	14 Oct 2020 14:36:29

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Oct 2020 14:36:30
	(b) (4)	

**US3042241**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:11
User entered '1'	(b) (4), (b) (6) System	14 Oct 2020 14:36:30

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 64'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-10-19T23:00:58', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7f36d01e-5f49-45ce-ad5c-ded2044d3300' User entered 'No (N)'	(b) (4), (b) (6) System	20 Oct 2020 04:01:10
	System	20 Oct 2020 04:01:10

US3042241

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:53:57

Have you been exposed to someone with 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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-10-19T23:01:01', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7f36d01e-5f49-45ce-ad5c-ded2044d3300'	(b) (4), (b) (6)	
	System	20 Oct 2020 04:01:10
User entered 'No (N)'	System	20 Oct 2020 04:01:10

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-10-19T23:01:04', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7f36d01e-5f49-45ce-ad5c-ded2044d3300' User entered '19 Oct 2020 23:01:04'	(b) (4), (b) (6) System	20 Oct 2020 04:01:10
	System	20 Oct 2020 04:01:10



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 71'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-10-26T19:09:19', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9a07c298-4cde-4767-b0e6-0ba02998fd34'	(b) (4), (b) (6)	27 Oct 2020 00:09:27
User entered 'No (N)'	System	27 Oct 2020 00:09:27

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-10-26T19:09:23', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9a07c298-4cde-4767-b0e6-0ba02998fd34'	(b) (4), (b) (6)	27 Oct 2020 00:09:27
User entered 'No (N)'	System	27 Oct 2020 00:09:27

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-10-26T19:09:25', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '9a07c298-4cde-4767-b0e6-0ba02998fd34' User entered '26 Oct 2020 19:09:25'	(b) (4), (b) (6) System	27 Oct 2020 00:09:27
	System	27 Oct 2020 00:09:27

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 19:38:25



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 78'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-02T06:43:52', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '47bba416-6a24-46a2-b506-8f0845466a20' User entered 'No (N)'	(b) (4), (b) (6) System	02 Nov 2020 12:44:09
	System	02 Nov 2020 12:44:09

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-02T06:44:01', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '47bba416-6a24-46a2-b506-8f0845466a20' User entered 'No (N)'	(b) (4), (b) (6) System	02 Nov 2020 12:44:09
	System	02 Nov 2020 12:44:09

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-02T06:44:04', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '47bba416-6a24-46a2-b506-8f0845466a20' User entered '02 Nov 2020 06:44:04'	(b) (4), (b) (6) System	02 Nov 2020 12:44:09
	System	02 Nov 2020 12:44:09

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered 'Day 92'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-16T00:01:14', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a7f71934-f848-44a9-ac03-5fad7a144d31'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Nov 2020 06:01:36



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-16T00:01:25', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a7f71934-f848-44a9-ac03-5fad7a144d31'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Nov 2020 06:01:36

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-16T00:01:27', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a7f71934-f848-44a9-ac03-5fad7a144d31' User entered '16 Nov 2020 00:01:27'	(b) (4), (b) (6) System	16 Nov 2020 06:01:36
	System	16 Nov 2020 06:01:36

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:55:29
	(b) (4), (b) (6)	
Data entry locked.	System	19 Aug 2020 19:38:25
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 19:38:25

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-23T04:39:21', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e582f174-140a-4898-af48-7ca0773bb7b2'	System	23 Nov 2020 10:39:30
User entered 'No (N)'	System	23 Nov 2020 10:39:30

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-23T04:39:23', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e582f174-140a-4898-af48-7ca0773bb7b2'	System	23 Nov 2020 10:39:30
User entered 'No (N)'	System	23 Nov 2020 10:39:30

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-23T04:39:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e582f174-140a-4898-af48-7ca0773bb7b2'	System	23 Nov 2020 10:39:30
User entered '23 Nov 2020 04:39:26'	System	23 Nov 2020 10:39:30



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-27T00:01:27', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '863cab9-e49b-4ecd-9fd4-8fb3ad35dddc' User entered 'No (N)'	System	27 Nov 2020 06:02:02
	System	27 Nov 2020 06:02:02

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-27T00:01:52', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '863cab9-e49b-4ecd-9fd4-8fb3ad35dddc'	System	27 Nov 2020 06:02:02
User entered 'No (N)'	System	27 Nov 2020 06:02:02

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-11-27T00:01:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '863cab9-e49b-4ecd-9fd4-8fb3ad35dddc' User entered '27 Nov 2020 00:01:55'	System	27 Nov 2020 06:02:02
	System	27 Nov 2020 06:02:02

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-04T01:53:03', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '631e9a34-3c68-4792-8ce7-a9238c489be8' User entered 'No (N)'	System	04 Dec 2020 07:53:12
	System	04 Dec 2020 07:53:12

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-04T01:53:05', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '631e9a34-3c68-4792-8ce7-a9238c489be8' User entered 'No (N)'	System	04 Dec 2020 07:53:12

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-04T01:53:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '631e9a34-3c68-4792-8ce7-a9238c489be8' User entered '04 Dec 2020 01:53:10'	System	04 Dec 2020 07:53:12
	System	04 Dec 2020 07:53:12

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-11T05:05:24', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '2a1650bd-80e4-473f-b136-04444836cb52'	System	11 Dec 2020 11:05:32
User entered 'No (N)'	System	11 Dec 2020 11:05:32



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-11T05:05:26', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '2a1650bd-80e4-473f-b136-04444836cb52'	System	11 Dec 2020 11:05:32
User entered 'No (N)'	System	11 Dec 2020 11:05:32

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-11T05:05:30', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '2a1650bd-80e4-473f-b136-04444836cb52'	System	11 Dec 2020 11:05:32
User entered '11 Dec 2020 05:05:30'	System	11 Dec 2020 11:05:32

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-18T00:01:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '959584b0-d968-43a6-9cda-899237886691'	System	18 Dec 2020 06:01:19
User entered 'No (N)'	System	18 Dec 2020 06:01:19

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-18T00:01:12', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '959584b0-d968-43a6-9cda-899237886691'	System	18 Dec 2020 06:01:19
User entered 'No (N)'	System	18 Dec 2020 06:01:19

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-18T00:01:14', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '959584b0-d968-43a6-9cda-899237886691' User entered '18 Dec 2020 00:01:14'	System	18 Dec 2020 06:01:19
	System	18 Dec 2020 06:01:19



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:02', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered 'Yes (Y)'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:23', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered 'Yes (Y)'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Please 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:25', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:30', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered 'Yes (Y)'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23' User entered '0'	System	25 Dec 2020 18:33:00
	System	25 Dec 2020 18:33:00



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '1'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '1'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '1'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '0'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '1'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '1'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '1'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '0'	System	25 Dec 2020 18:33:00



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '0'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '1'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '0'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '1'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '1'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '0'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered '0'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:43', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23' User entered '0'	System	25 Dec 2020 18:33:00
	System	25 Dec 2020 18:33:00



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Please 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:45', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:46', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered 'Yes (Y)'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Please 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:48', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23'	System	25 Dec 2020 18:33:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2020-12-25T12:32:50', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'f3554a0b-e917-4bfb-b05f-c542a25d2b23' User entered '25 Dec 2020 12:32:50'	System	25 Dec 2020 18:33:00
	System	25 Dec 2020 18:33:00

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-03T13:02:59', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '63f5cf6f-5557-4dc8-b57e-4030a5c1bee2'	System	03 Jan 2021 19:03:07
User entered 'No (N)'	System	03 Jan 2021 19:03:07



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-03T13:03:01', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '63f5cf6f-5557-4dc8-b57e-4030a5c1bee2'	System	03 Jan 2021 19:03:07
User entered 'No (N)'	System	03 Jan 2021 19:03:07

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-03T13:03:03', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '63f5cf6f-5557-4dc8-b57e-4030a5c1bee2' User entered '03 Jan 2021 13:03:03'	System	03 Jan 2021 19:03:07
	System	03 Jan 2021 19:03:07

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-09T19:15:06', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7c4bf649-cc06-4adc-a5be-aa0f831c998d' User entered 'No (N)'	System	12 Jan 2021 08:11:46
	System	12 Jan 2021 08:11:46

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-09T19:15:14', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7c4bf649-cc06-4adc-a5be-aa0f831c998d'	System	12 Jan 2021 08:11:46
User entered 'No (N)'	System	12 Jan 2021 08:11:46

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-09T19:15:17', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7c4bf649-cc06-4adc-a5be-aa0f831c998d' User entered '09 Jan 2021 19:15:17'	System	12 Jan 2021 08:11:46
	System	12 Jan 2021 08:11:46



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-15T00:01:55', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1ba558c9-2c82-455a-b8fd-538f9ff6c9d0'	System	15 Jan 2021 06:02:11
User entered 'No (N)'	System	15 Jan 2021 06:02:11

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-15T00:01:57', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1ba558c9-2c82-455a-b8fd-538f9ff6c9d0'	System	15 Jan 2021 06:02:11
User entered 'No (N)'	System	15 Jan 2021 06:02:11

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-15T00:02:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '1ba558c9-2c82-455a-b8fd-538f9ff6c9d0'	System	15 Jan 2021 06:02:11
User entered '15 Jan 2021 00:02:00'	System	15 Jan 2021 06:02:11

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-22T01:42:49', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '24457a92-a7f4-47b8-bdea-94d8d471f37e' User entered 'No (N)'	System	22 Jan 2021 07:42:55
	System	22 Jan 2021 07:42:55

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-22T01:42:51', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '24457a92-a7f4-47b8-bdea-94d8d471f37e' User entered 'No (N)'	System	22 Jan 2021 07:42:55
	System	22 Jan 2021 07:42:55

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-22T01:42:53', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '24457a92-a7f4-47b8-bdea-94d8d471f37e' User entered '22 Jan 2021 01:42:53'	System	22 Jan 2021 07:42:55
	System	22 Jan 2021 07:42:55

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-29T08:59:52', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '06faa244-d47f-4723-9ee5-aedde8d13f5d'	System	29 Jan 2021 14:59:59
User entered 'No (N)'	System	29 Jan 2021 14:59:59



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-29T08:59:53', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '06faa244-d47f-4723-9ee5-aedde8d13f5d'	System	29 Jan 2021 14:59:59
User entered 'No (N)'	System	29 Jan 2021 14:59:59

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-01-29T08:59:56', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '06faa244-d47f-4723-9ee5-aedde8d13f5d' User entered '29 Jan 2021 08:59:56'	System	29 Jan 2021 14:59:59

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-07T12:00:17', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '52759a35-cf06-410a-9fc0-dd733c229fcc' User entered 'No (N)'	System	07 Feb 2021 18:00:30
	System	07 Feb 2021 18:00:30

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-07T12:00:18', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '52759a35-cf06-410a-9fc0-dd733c229fcc' User entered 'No (N)'	System	07 Feb 2021 18:00:30

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-07T12:00:21', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '52759a35-cf06-410a-9fc0-dd733c229fcc' User entered '07 Feb 2021 12:00:21'	System	07 Feb 2021 18:00:30
	System	07 Feb 2021 18:00:30



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-12T00:01:10', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '901ce29b-de8b-441e-b4bd-99ec00818178' User entered 'No (N)'	System	12 Feb 2021 06:01:20
	System	12 Feb 2021 06:01:20

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-12T00:01:11', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '901ce29b-de8b-441e-b4bd-99ec00818178'	System	12 Feb 2021 06:01:20
User entered 'No (N)'	System	12 Feb 2021 06:01:20

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-12T00:01:13', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '901ce29b-de8b-441e-b4bd-99ec00818178' User entered '12 Feb 2021 00:01:13'	System	12 Feb 2021 06:01:20
	System	12 Feb 2021 06:01:20

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-19T07:38:28', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e0b0b615-dbd0-4108-9f03-ff5b3a65220a' User entered 'No (N)'	System	19 Feb 2021 13:38:40
	System	19 Feb 2021 13:38:40

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-19T07:38:30', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e0b0b615-dbd0-4108-9f03-ff5b3a65220a' User entered 'No (N)'	System	19 Feb 2021 13:38:40
	System	19 Feb 2021 13:38:40

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-19T07:38:33', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'e0b0b615-dbd0-4108-9f03-ff5b3a65220a' User entered '19 Feb 2021 07:38:33'	System	19 Feb 2021 13:38:40
	System	19 Feb 2021 13:38:40

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-26T00:40:30-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a4c4c7e1-8932-40b6-a4cd-2b5f6560b3a8'	System	26 Feb 2021 06:40:39
User entered 'No (N)'	System	26 Feb 2021 06:40:39



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-26T00:40:32-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a4c4c7e1-8932-40b6-a4cd-2b5f6560b3a8'	System	26 Feb 2021 06:40:39
User entered 'No (N)'	System	26 Feb 2021 06:40:39

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-02-26T00:40:34-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'a4c4c7e1-8932-40b6-a4cd-2b5f6560b3a8' User entered '26 Feb 2021 06:40:34'	System	26 Feb 2021 06:40:39
	System	26 Feb 2021 06:40:39

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-05T00:04:06-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '734ef6b8-0bab-46f8-a49b-b4a0232aa006'	System	05 Mar 2021 06:04:13
User entered 'No (N)'	System	05 Mar 2021 06:04:13

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-05T00:04:07-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '734ef6b8-0bab-46f8-a49b-b4a0232aa006'	System	05 Mar 2021 06:04:13
User entered 'No (N)'	System	05 Mar 2021 06:04:13

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-05T00:04:09-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '734ef6b8-0bab-46f8-a49b-b4a0232aa006'	System	05 Mar 2021 06:04:13
User entered '05 Mar 2021 00:04:09'	System	05 Mar 2021 06:04:13



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-12T00:03:14-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'c72121b5-b436-4237-93ad-12ff347b6215'	System	12 Mar 2021 06:03:20
User entered 'No (N)'	System	12 Mar 2021 06:03:20

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-12T00:03:15-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'c72121b5-b436-4237-93ad-12ff347b6215'	System	12 Mar 2021 06:03:20
User entered 'No (N)'	System	12 Mar 2021 06:03:20

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-12T00:03:18-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'c72121b5-b436-4237-93ad-12ff347b6215'	System	12 Mar 2021 06:03:20
User entered '12 Mar 2021 00:03:18'	System	12 Mar 2021 06:03:20

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-19T09:31:27-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'aed6102e-e4e0-4839-aad2-bcbbe1cccad0'	System	19 Mar 2021 14:31:49
User entered 'No (N)'	System	19 Mar 2021 14:31:49

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-19T09:31:29-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'aed6102e-e4e0-4839-aad2-bcbbe1cccad0'	System	19 Mar 2021 14:31:49
User entered 'No (N)'	System	19 Mar 2021 14:31:49

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-19T09:31:44-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'aed6102e-e4e0-4839-aad2-bcbbe1cccad0' User entered '19 Mar 2021 09:31:44'	System	19 Mar 2021 14:31:49
	System	19 Mar 2021 14:31:49

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-26T12:50:26-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7b32d090-26ee-4d5f-9221-90860f7526d2'	System	26 Mar 2021 17:50:53
User entered 'Yes (Y)'	System	26 Mar 2021 17:50:53



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-26T12:50:29-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7b32d090-26ee-4d5f-9221-90860f7526d2'	System	26 Mar 2021 17:50:53
User entered 'No (N)'	System	26 Mar 2021 17:50:53

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-26T12:50:32-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7b32d090-26ee-4d5f-9221-90860f7526d2'	System	26 Mar 2021 17:50:53
User entered 'No (N)'	System	26 Mar 2021 17:50:53

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-26T12:50:42-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7b32d090-26ee-4d5f-9221-90860f7526d2'	System	26 Mar 2021 17:50:53
User entered 'No (N)'	System	26 Mar 2021 17:50:53

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-26T12:50:49-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '7b32d090-26ee-4d5f-9221-90860f7526d2' User entered '26 Mar 2021 12:50:49'	System	26 Mar 2021 17:50:53
	System	26 Mar 2021 17:50:53

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-05T11:05:30-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '37247b00-0edb-414e-a01c-fc8cc63f85e8'	System	05 Apr 2021 16:12:29
User entered 'No (N)'	System	05 Apr 2021 16:12:29



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-05T11:05:31-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '37247b00-0edb-414e-a01c-fc8cc63f85e8'	System	05 Apr 2021 16:12:29
User entered 'No (N)'	System	05 Apr 2021 16:12:29

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-05T11:05:33-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '37247b00-0edb-414e-a01c-fc8cc63f85e8'	System	05 Apr 2021 16:12:29
User entered '05 Apr 2021 11:05:33'	System	05 Apr 2021 16:12:29

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-11T12:00:21-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '98b94ac1-5ea7-4a7a-8718-41c0b89f7f08'	System	11 Apr 2021 17:00:30
User entered 'No (N)'	System	11 Apr 2021 17:00:30

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-11T12:00:24-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '98b94ac1-5ea7-4a7a-8718-41c0b89f7f08'	System	11 Apr 2021 17:00:30
User entered 'No (N)'	System	11 Apr 2021 17:00:30

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-11T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '98b94ac1-5ea7-4a7a-8718-41c0b89f7f08'	System	11 Apr 2021 17:00:30
User entered '11 Apr 2021 12:00:26'	System	11 Apr 2021 17:00:30



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-18T15:30:32-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '91317937-684b-4e2e-8269-4895b7e40734'	System	18 Apr 2021 20:30:40
User entered 'No (N)'	System	18 Apr 2021 20:30:40

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-18T15:30:34-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '91317937-684b-4e2e-8269-4895b7e40734'	System	18 Apr 2021 20:30:40
User entered 'No (N)'	System	18 Apr 2021 20:30:40

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-18T15:30:36-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: '91317937-684b-4e2e-8269-4895b7e40734'	System	18 Apr 2021 20:30:40
User entered '18 Apr 2021 15:30:36'	System	18 Apr 2021 20:30:40

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-25T12:00:11-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'd641e8b1-fd05-4119-8c19-4b1b83069dda' User entered 'No (N)'	System	25 Apr 2021 17:00:24
	System	25 Apr 2021 17:00:24

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-25T12:00:13-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'd641e8b1-fd05-4119-8c19-4b1b83069dda'	System	25 Apr 2021 17:00:24
User entered 'No (N)'	System	25 Apr 2021 17:00:24

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-04-25T12:00:15-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'd641e8b1-fd05-4119-8c19-4b1b83069dda' User entered '25 Apr 2021 12:00:15'	System	25 Apr 2021 17:00:24
	System	25 Apr 2021 17:00:24

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-05-03T17:59:22-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'da7b3011-e050-428f-b88a-03be1ead8944'	System	03 May 2021 22:59:58
User entered 'Yes (Y)'	System	03 May 2021 22:59:58



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Have you been exposed to someone with 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-05-03T17:59:25-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'da7b3011-e050-428f-b88a-03be1ead8944'	System	03 May 2021 22:59:58
User entered 'No (N)'	System	03 May 2021 22:59:58

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-05-03T17:59:32-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'da7b3011-e050-428f-b88a-03be1ead8944'	System	03 May 2021 22:59:58
User entered 'No (N)'	System	03 May 2021 22:59:58

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-05-03T17:59:38-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'da7b3011-e050-428f-b88a-03be1ead8944'	System	03 May 2021 22:59:58
User entered 'Yes (Y)'	System	03 May 2021 22:59:58

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

Please 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 (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-05-03T17:59:45-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'da7b3011-e050-428f-b88a-03be1ead8944'	System	03 May 2021 22:59:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 May 2021 22:59:58

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-05-03T17:59:47-05:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'da7b3011-e050-428f-b88a-03be1ead8944'	System	03 May 2021 22:59:58
User entered '03 May 2021 17:59:47'	System	03 May 2021 22:59:58

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:15:35

**US3042241**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:15:35



**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:15:35



**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:15:35



**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:15:35



**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:15:35



**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:15:35



**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:15:35



**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:15:35

**US3042241**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:53:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:35
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:15:35

US3042241

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:53:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-05T00:04:15-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'b6852d78-0906-466c-91d8-21e8d364cb89'	System	05 Mar 2021 06:04:18
User entered 'No (N)'	System	05 Mar 2021 06:04:18

**US3042241**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:43:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (003FA049-9CEE-47AA-A62B-A563E19D1292)', Time: '2021-03-05T00:04:17-06:00', User OID: 'PatientReportedOutcome (US3042241)', ODM File OID: 'b6852d78-0906-466c-91d8-21e8d364cb89'	System	05 Mar 2021 06:04:18
User entered '05 Mar 2021 00:04:17'	System	05 Mar 2021 06:04:18



**US3042241**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:45:57

**US3042241**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:45:57

**US3042241**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:45:57

**US3042241**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:45:57

**US3042241**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:41
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:46:03

**US3042241**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:41
User entered 'I'	(b) (4), (b) (6) System	09 Nov 2020 21:46:03

**US3042241**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:15:12

**US3042241**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:15:12



**US3042241**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Dec 2020 20:15:12

**US3042241**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:15:12

**US3042241**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:15:18

**US3042241**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User entered 'I'	(b) (4), (b) (6) System	14 Dec 2020 20:15:18

**US3042241**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:21

**US3042241**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:21

**US3042241**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:21

**US3042241**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'patient in convalescent phase'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:21



**US3042241**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:31

**US3042241**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User entered '1'	(b) (4), (b) (6) System	10 Feb 2021 18:31:31

**US3042241**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:44

**US3042241**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:44

**US3042241**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Feb 2021 18:31:44

**US3042241**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:44

**US3042241**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:31:50

**US3042241**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:50:51
User entered '1'	(b) (4), (b) (6) System	10 Feb 2021 18:31:50



**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:10:10

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '17 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:10:10

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[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 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:10:10

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User entered 'VISIT4'	(b) (4), (b) (6) System	17 Mar 2021 15:10:10

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:56:03



**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03



**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:56:03

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:50:14

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:50:14

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:10:13

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:10:13

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:10:19



**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '17 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:10:19

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '09:50'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:10:19

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User entered '17 Mar 2021 09:50'	(b) (4), (b) (6) System	17 Mar 2021 15:10:19

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:10:21

**US3042241**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:14
User entered 'I'	(b) (4), (b) (6) System	17 Mar 2021 15:10:21

**US3042241**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:37:19

**US3042241**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:37:19

**US3042241**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:37:19



**US3042241**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:53:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:37:19

**US3042241**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:37:26

**US3042241**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:53:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:37:26

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:57

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User closed query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24DEC2020, 27DEC2020 29DEC2020, 01JAN2021, 06JAN2021 and 20JAN2021labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then initiate an Illness visit and record the data on the Saliva collection form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 05:47:07
Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24DEC2020, 27DEC2020 29DEC2020, 01JAN2021, 06JAN2021 and 20JAN2021labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then initiate an Illness visit and record the data on the Saliva collection form. Thank you.' answered with 'FORM HAS BEEN UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:27
User opened query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24DEC2020, 27DEC2020 29DEC2020, 01JAN2021, 06JAN2021 and 20JAN2021labelled as Illness Visit which is missing in EDC. Please confirm if the sample was collected then initiate an Illness visit and record the data on the Saliva collection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:28:41
Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24DEC2020, 27DEC2020 29DEC2020, 01JAN2021, 06JAN2021 and 20JAN2021labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:28:07

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:53:57

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24DEC2020, 27DEC2020 29DEC2020, 01JAN2021, 06JAN2021 and 20JAN2021labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 10:27:59
	(b) (4), (b) (6)	08 Jan 2021 19:27:25
User entered '23 Dec 2020'	Jamie Thompson (b) (4)	23 Dec 2020 18:30:47
	(b) (4)	

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:53:57**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:25
User entered '11:35'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:30:47

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:53:57**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '23 Dec 2020 11:35'	(b) (4), (b) (6) System	23 Dec 2020 18:30:47

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:53:57**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:25
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:30:47



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:53:57**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:25
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:30:47

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 1 (Day 1)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:57

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '20 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4)	23 Dec 2020 18:40:54
	(b) (4)	
User entered '20 Nov 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4)	23 Dec 2020 18:31:33
	(b) (4)	
User entered '19 Nov 2020'	Jamie Thompson (b) (4)	23 Dec 2020 18:31:04
	(b) (4)	

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'l'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 2 (Day 2)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '21 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:40:54
User entered '21 Nov 2020'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'l'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:33

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 3 (Day 3)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:57

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '22 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:40:54
User entered '22 Nov 2020'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:57

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 23 Dec 2020 symptom log on log line 3. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:42:33
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:50:08
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 23 Dec 2020 symptom log on log line 3. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	21 Apr 2021 18:48:53
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	21 Apr 2021 18:48:39
User entered '1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	21 Apr 2021 18:48:39
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 23 Dec 2020 symptom log on log line 3. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 06:32:17
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 18:31:46

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:57

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:31:46

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 4 (Day 4)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '23 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:40:54
User entered '23 Nov 2020'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '99'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	23 Dec 2020 18:33:04



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '37.2' C	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:33:04

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 5 (Day 5)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '24 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98.4' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:57

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:48:59

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 6 (Day 6)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '25 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '97.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:49:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 7 (Day 7)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '26 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '97'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98.4' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:50:21

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 8 (Day 8)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '27 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '99'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	28 Dec 2020 18:51:34



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98.2' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:51:34

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 9 (Day 9)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '28 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '97.7' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 10 (Day 10)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '29 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '96'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	30 Dec 2020 23:07:49

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:07:49

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 11 (Day 11)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '30 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '96'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	30 Dec 2020 23:08:27

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98.4' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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**Form: Symptom Log (11)**

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 23:08:27

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 12 (Day 12)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '31 Dec 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '96'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	04 Jan 2021 16:59:38



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98.2' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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Form: Symptom Log (12)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (12)**

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38



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Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 16:59:38

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 13 (Day 13)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '01 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '96'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	04 Jan 2021 17:00:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98.2' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:00:20

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 14 (Day 14)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '02 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '95'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	04 Jan 2021 17:01:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98.8' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 15 (Day 15)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '03 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:01:44

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 16 (Day 16)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '04 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '97'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	04 Jan 2021 17:02:35



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '101.0' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 17 (Day 17)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '05 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '96'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '99.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:30:51

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 18 (Day 18)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '06 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '96.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:53:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:21:39

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 19 (Day 19)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '07 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '99'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	07 Jan 2021 17:19:16

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 20 (Day 20)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '08 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98'	Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	08 Jan 2021 16:59:20



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered '98.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	08 Jan 2021 16:59:20

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 21 (Day 21)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '09 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '98'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:46:40

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 22 (Day 22)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '10 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	11 Jan 2021 18:47:24

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24



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Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:47:24

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 23 (Day 23)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '11 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '96'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	11 Jan 2021 18:48:37

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37



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Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	11 Jan 2021 18:48:37

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 24 (Day 24)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '12 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '98'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	12 Jan 2021 21:26:03



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '98.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 21:26:03

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 25 (Day 25)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '13 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '98'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	13 Jan 2021 21:55:29

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97.4' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:55:29

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 26 (Day 26)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '14 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '98'	Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	14 Jan 2021 18:43:13

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97.4' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (26)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Jan 2021 18:43:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 27 (Day 27)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '15 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '98'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	18 Jan 2021 20:46:26

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26



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Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:46:26

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 28 (Day 28)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '16 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '98'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	18 Jan 2021 20:47:01



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '96.8' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:01

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 29 (Day 29)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '17 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	18 Jan 2021 20:47:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97.5' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:47:35

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 30 (Day 30)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07



**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '18 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '97'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	18 Jan 2021 20:48:07

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered '98.9' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07



US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07



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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (30)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:21:28
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	18 Jan 2021 20:48:07

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:48
User entered '23 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:41:08
User entered '23 Nov 2020'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:30

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[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 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:48
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:30

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:57

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 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:48
User closed query 'Per CDM: Response noted, However there is no AE available for Covid-19. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 07:26:51
Query 'Per CDM: Response noted, However there is no AE available for Covid-19. Kindly review and update accordingly. Thank you.' answered with 'AE HAS BEEN ADDED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 20:15:26
User opened query 'Per CDM: Response noted, However there is no AE available for Covid-19. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 05:42:11
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	05 Jan 2021 05:40:25
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE UPDATED' (Site from System).	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:48
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	04 Jan 2021 17:02:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:02:45
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Dec 2020 22:20:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Dec 2020 22:20:42
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	24 Dec 2020 22:20:42
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 18:34:30



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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:57

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:30

US3042241

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:57

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "SAMPLE IS RECORDED IN PPD." & swab sample dated 23-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 10:48:01
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:27:48
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "SAMPLE IS RECORDED IN PPD." & swab sample dated 23-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '28DEC2020 SHIPMENT TRACKING NUMBERS: 923173282385 AND 923173283602.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 19:23:43
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "SAMPLE IS RECORDED IN PPD." & swab sample dated 23-DEC-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 06:15:13

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:57

[Date of Test](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection Date 23DEC2020 is reported under Covid-19 Assessment in EDC. However the same is missing in PPD Central lab. Please confirm and update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 06:15:13
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection Date 23DEC2020 is reported under Covid-19 Assessment in EDC. However the same is missing in PPD Central lab. Please confirm and update the data as appropriate.' answered with 'SAMPLE IS RECORDED IN PPD.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:53:48
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample Collection Date 23DEC2020 is reported under Covid-19 Assessment in EDC. However the same is missing in PPD Central lab. Please confirm and update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:30:24
User entered '23 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:41:08
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 18:34:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 18:34:54
User entered '23 Nov 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:54
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 18:34:30
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:30

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: COVID Diagnostic Test**

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:48
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:30

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:48
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:30

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Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:57

[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 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:48
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 18:34:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 18:34:54
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:54
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 18:34:30
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:30

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**Folder: Covid-19 Assessment 23 Dec 2020**

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:48
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:30

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: COVID Diagnostic Test**

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:48
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:34:30



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Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:53:57

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '1'	(b) (4), (b) (6)	04 Jan 2021 17:02:45
User entered '0'	System	24 Dec 2020 22:20:42

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Did the subject have Respiratory Rates  \$\geq\$  30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:57

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:30:36
User closed query 'Per CDM: Did the subject have Heart Rate $\geq$ 125 beats per minute is marked YES, However start and end date are missing. Please review and reconcile. Else clarify' (Site from DM). Query 'Per CDM: Did the subject have Heart Rate $\geq$ 125 beats per minute is marked YES, However start and end date are missing. Please review and reconcile. Else clarify' answered with 'ENTRY UPDATED' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 11:42:55
User opened query 'Per CDM: Did the subject have Heart Rate $\geq$ 125 beats per minute is marked YES, However start and end date are missing. Please review and reconcile. Else clarify' (Site from DM). DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 14:14:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	09 Apr 2021 05:07:07
DataPoint Verified.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
	(b) (4), (b) (6)	08 Jan 2021 19:28:04
	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:57

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:30:51
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 14:14:42
User entered '24 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 14:14:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:57

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:30:52
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 14:14:42
User entered '24 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Apr 2021 14:14:42
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12



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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:30:57
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
User entered '137' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12



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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Form: Covid-19 Severity Assessment**

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12



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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12



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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:57

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

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**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12



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**Folder: Covid-19 Assessment 23 Dec 2020**

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**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:57

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:26
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:57

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:27
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
User entered '06 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:53:57

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:29
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12



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Folder: Covid-19 Assessment 23 Dec 2020

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Generated On: 11 Aug 2021 21:53:57

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:32:31
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
User entered '06 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:34:49
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

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**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

**US3042241**

**Folder: Covid-19 Assessment 23 Dec 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Jan 2021 17:03:12

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:25
User entered '30 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:15:42

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:53:57**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:25
User entered '14:17'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:15:42

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:53:57**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '30 Sep 2020 14:17'	(b) (4), (b) (6) System	06 Oct 2020 15:15:42

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:53:57**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:25
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:15:42



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:53:57**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:25
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:15:42

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Day 4 (Day 4)' reason for change:	Rylea Gulick (b) (4)	04 Nov 2020 21:15:57
Data Entry Error	(b) (4)	
User entered 'Day 1 (Day 1)'	Rylea Gulick (b) (4)	06 Oct 2020 15:16:53
	(b) (4)	

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '30 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '98'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '36.9' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53



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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53



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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:53

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Day 5 (Day 5)' reason for change:	Rylea Gulick (b) (4)	04 Nov 2020 21:15:57
Data Entry Error	(b) (4)	
User entered 'Day 2 (Day 2)'	Rylea Gulick (b) (4)	06 Oct 2020 15:17:42
	(b) (4)	



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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '01 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '98'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	06 Oct 2020 15:17:42

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '98.3' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42



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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42



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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:17:42

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	04 Nov 2020 21:15:57
User entered 'Day 3 (Day 3)'	(b) (4) Rylea Gulick (b) (4)	06 Oct 2020 15:18:29

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '02 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '0'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29



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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '98'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '96.8' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29



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Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29



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Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:29

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change:	Rylea Gulick (b) (4)	04 Nov 2020 21:15:57
Data Entry Error	(b) (4)	
User entered 'Day 4 (Day 4)'	Rylea Gulick (b) (4)	06 Oct 2020 15:18:45
	(b) (4)	

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '03 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered empty.	(b) (4), (b) (6) System	06 Oct 2020 15:18:45



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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45



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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45



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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:53:57

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:45

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Rylea Gulick (b) (4)	04 Nov 2020 21:15:57
User entered 'Day 5 (Day 5)'	(b) (4) Rylea Gulick (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '04 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'l'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered empty.	(b) (4), (b) (6) System	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:18:58

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User closed query 'Per CDM: Both Log Line #4 and Log Line #6 have been labeled as Symptom Day 7. Please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 01:53:42
Query 'Per CDM: Both Log Line #4 and Log Line #6 have been labeled as Symptom Day 7. Please reconcile.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:22:28
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 21:22:18
User opened query 'Per CDM: Both Log Line #4 and Log Line #6 have been labeled as Symptom Day 7. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 19:11:14
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:15:57
User entered 'Day 6 (Day 6)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44



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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '05 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '98'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6) System	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '98.6' F	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44



US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Moderate (Moderate)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:19:44

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 1 (Day 1)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '27 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '0'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19



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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User closed query 'Per CDM: Please complete the O2 Saturation and Temperature fields on log lines 7,8,9. If Not done, please type "ND" in these fields. Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 07:34:08
Query 'Per CDM: Please complete the O2 Saturation and Temperature fields on log lines 7,8,9. If Not done, please type "ND" in these fields. Thank you. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 21:21:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 21:21:41
User opened query 'Per CDM: Please complete the O2 Saturation and Temperature fields on log lines 7,8,9. If Not done, please type "ND" in these fields. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:42:26
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6)	02 Dec 2020 21:21:41
User entered empty.	System	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 21:21:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19



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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:57

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 2 (Day 2)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '28 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '0'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 21:21:56
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

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**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6)	02 Dec 2020 21:21:56
User entered empty.	System	04 Nov 2020 21:19:19



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 21:21:56
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:57

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
User entered 'Day 3 (Day 3)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '29 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered '0'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 21:22:04
User entered empty.	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '%'	(b) (4), (b) (6)	02 Dec 2020 21:22:04
User entered empty.	System	04 Nov 2020 21:19:19

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Rylea Gulick (b) (4)	02 Dec 2020 21:22:04
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19



US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

US3042241

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:53:57

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'None (None)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:32
User entered 'Mild (Mild)'	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 21:19:19

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:55
User entered '30 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:02



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[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 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:55
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:02

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[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 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:55
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:02

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:55
User entered '30 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:02

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:02

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:02

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[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 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:55
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:02

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:02

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:55
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:16:02



**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:53:57**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User entered '0'	(b) (4), (b) (6) System	06 Oct 2020 15:16:02

**US3042241**

**Folder: Covid-19 Assessment 30 Sep 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 11 Aug 2021 21:53:57**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:56:59
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:11
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:10:20

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered 'NA (COVID-19 Negative) (NA)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered 'NA (COVID-19 Negative) (NA)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48



**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered 'NA (COVID-19 Negative) (NA)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered 'NA (COVID-19 Negative) (NA)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered 'NA (COVID-19 Negative) (NA)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48



**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered 'NA (COVID-19 Negative) (NA)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered 'NA (COVID-19 Negative) (NA)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:41:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:21:48

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58



**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

US3042241

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:53:57

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F633614046 is reported with 24DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 07:10:25
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F633614046 is reported with 24DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	05 Feb 2021 17:32:24
User entered '24 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	05 Feb 2021 17:32:18
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F633614046 is reported with 24DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:18:28
User entered '25 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

US3042241

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:53:57

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F655160340is reported with 27DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 07:04:42
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F655160340is reported with 27DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with '27DEC2020 WAS WHEN SAMPLE WAS RETURNED TO LAB' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 19:13:25
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F655160340is reported with 27DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:30:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered '26 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	05 Feb 2021 17:32:33
User entered '27 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

US3042241

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:53:57

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F638396502 is reported with 29DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day 7 to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:17:15
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F638396502 is reported with 29DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day 7 to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' answered with 'COLLECTION DATE CANNOT BE CHANGED IN PPD' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	23 Mar 2021 15:52:49
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F638396502 is reported with 29DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the "correct date" for Day 7 to be updated in the PPD. Please note that Collection date should be same in the EDC and Precalrus report. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 17:52:41
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F638396502 is reported with 29DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 07:04:48

US3042241

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:53:57

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F638396502 is reported with 29DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with '29DEC2020 WAS WHEN SAMPLE WAS RETURNED TO LAB' (Site from DM).	Rylea Gulick (b) (4)	02 Mar 2021 19:13:43
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F638396502 is reported with 29DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:31:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Jan 2021 16:00:03
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Jan 2021 16:37:58



**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered '28 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	05 Feb 2021 17:32:42
User entered '29 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F633830552 is reported with 01JAN2021 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:32:22
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F633830552 is reported with 01JAN2021 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 05:11:40
User accepted default value 'Day 9 (Day 9)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

US3042241

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:53:57

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User closed query ' Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F652994774 is reported with 01JAN2021 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 07:04:54
Query ' Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F652994774 is reported with 01JAN2021 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 19:14:00
User opened query ' Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F652994774 is reported with 01JAN2021 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:32:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered '01 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 19:13:54
User entered '30 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	05 Feb 2021 17:33:02
User entered '01 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered '06 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

US3042241

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:53:57

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated Day 21 13JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:31:48
Query 'Per GCL LAB reconciliation: Saliva: Sample dated Day 21 13JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	05 Feb 2021 17:33:37
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated Day 21 13JAN2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 17:20:02
User accepted default value 'Day 21 (Day 21)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58



**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	05 Feb 2021 17:33:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	05 Feb 2021 17:33:31
User entered '13 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit (2)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:30
User entered '20 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 16:00:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:37:58

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:28
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	06 Oct 2020 15:13:13
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:28
User entered '30 Sep 2020'	Rylea Gulick (b) (4)	06 Oct 2020 15:13:13
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[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 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:28
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	06 Oct 2020 15:13:13
	(b) (4)	



**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'SICKD1'	(b) (4), (b) (6) System	06 Oct 2020 15:13:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	06 Oct 2020 15:13:41
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered '30 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:13:41

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered '14:17'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:13:41

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered '30 Sep 2020 14:17'	(b) (4), (b) (6) System	06 Oct 2020 15:13:41

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered '165.1' cm	Rylea Gulick (b) (4)	06 Oct 2020 15:13:41
DataPoint set to visible.	(b) (4) System	06 Oct 2020 15:13:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered '86.7' kg	Rylea Gulick (b) (4)	06 Oct 2020 15:13:41
	(b) (4)	
DataPoint set to visible.	System	06 Oct 2020 15:13:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered '36.9' C	Rylea Gulick (b) (4)	06 Oct 2020 15:13:41
	(b) (4)	



**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:13:41

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered empty.	Rylea Gulick (b) (4)	06 Oct 2020 15:13:41
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered '82'	Rylea Gulick (b) (4)	06 Oct 2020 15:13:41
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'bpm'	(b) (4), (b) (6) System	06 Oct 2020 15:13:41

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered '12'	Rylea Gulick (b) (4)	06 Oct 2020 15:13:41
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'breaths/min'	(b) (4), (b) (6) System	06 Oct 2020 15:13:41

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered '102'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:13:41

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'mmHg'	(b) (4), (b) (6) System	06 Oct 2020 15:13:41



**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:36
User entered '72'	Rylea Gulick (b) (4)	06 Oct 2020 15:13:41
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'mmHg'	(b) (4), (b) (6) System	06 Oct 2020 15:13:41

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:16:54

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:16:54

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:47
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	06 Oct 2020 15:13:47
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:28:47
User entered '30 Sep 2020'	Rylea Gulick (b) (4)	06 Oct 2020 15:13:47
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 21:53:57**

[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 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:54
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:13:59

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:54
User entered '30 Sep 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Oct 2020 15:13:59



**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:34
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:36:12

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:29:34
User entered '23 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4)	23 Dec 2020 18:40:05
	(b) (4)	
User entered '23 Nov 2020'	Jamie Thompson (b) (4)	23 Dec 2020 18:36:12
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[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 14:16:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:29:34
User entered 'Clinic (Clinic)'	Jamie Thompson (b) (4)	23 Dec 2020 18:36:12
	(b) (4)	

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'SICKD1'	(b) (4), (b) (6) System	23 Dec 2020 18:36:12

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13

US3042241

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:57

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Dec 2020 18:40:13
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	23 Dec 2020 18:40:13
User entered '23 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:40:13
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Dec 2020 18:40:05
User entered '23 Nov 2020'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered '11:45'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
	(b) (4), (b) (6)	
User entered '23 Dec 2020 11:45'	System	23 Dec 2020 18:40:13
User entered '23 Nov 2020 11:45'	System	23 Dec 2020 18:37:13



**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered '165.1' cm	(b) (4) Jamie Thompson (b) (4)	23 Dec 2020 18:37:13
DataPoint set to visible.	(b) (4) System	23 Dec 2020 18:36:12

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered '87.2' kg	(b) (4) Jamie Thompson (b) (4)	23 Dec 2020 18:37:13
DataPoint set to visible.	(b) (4) System	23 Dec 2020 18:36:12

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered '37.2' C	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered 'Oral (Oral)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered '100'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'bpm'	(b) (4), (b) (6) System	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered '14'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13



**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'breaths/min'	(b) (4), (b) (6) System	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered '114'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'mmHg'	(b) (4), (b) (6) System	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:42
User entered '80'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered 'mmHg'	(b) (4), (b) (6) System	23 Dec 2020 18:37:13

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:16:54

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:16:54

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:56
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:28



US3042241

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:53:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:29:56
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Dec 2020 18:40:19
User entered '23 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:40:19
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Dec 2020 18:40:05
User entered '23 Nov 2020'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:28

**US3042241**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 21:53:57**

[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 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:03
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:42

US3042241

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:53:57

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:03
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 06:37:32
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'SAMPLE IS RECORDED IN PPD.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Dec 2020 14:54:42
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 12:19:23
User entered '23 Dec 2020' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:40:28
User entered '23 Nov 2020'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:37:42

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:23
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:30:44

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:23
User entered '20 Jan 2021'	Rylea Gulick (b) (4)	20 Jan 2021 16:30:44
	(b) (4)	

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[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 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:23
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:30:44

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:53:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User entered 'SICKD28'	(b) (4), (b) (6) System	20 Jan 2021 16:30:44

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:32
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:20



**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:32
User entered '20 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:32
User entered '08:11'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User entered '20 Jan 2021 08:11'	(b) (4), (b) (6) System	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:32
User entered '36.9' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:32
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:32
User entered empty.	Rylea Gulick (b) (4)	20 Jan 2021 16:31:20
	(b) (4)	

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:32
User entered '68'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User entered 'bpm'	(b) (4), (b) (6) System	20 Jan 2021 16:31:20



**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:45:32
User entered '12'	Rylea Gulick (b) (4)	20 Jan 2021 16:31:20
	(b) (4)	

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:32
User entered '114'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User entered 'mmHg'	(b) (4), (b) (6) System	20 Jan 2021 16:31:20

US3042241

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:53:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:32
User closed query 'Per CDM: Please reconcile. Consider updating BP to 70 mmHg rather than 070 mmHg. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:34:54
Query 'Per CDM: Please reconcile. Consider updating BP to 70 mmHg rather than 070 mmHg. Thank you. ' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	29 Jan 2021 20:21:49
User entered '70' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Jan 2021 20:21:45
User opened query 'Per CDM: Please reconcile. Consider updating BP to 70 mmHg rather than 070 mmHg. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:47:00
User entered '070'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User entered 'mmHg'	(b) (4), (b) (6) System	20 Jan 2021 16:31:20

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:28:26

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:53:57**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 14:28:26



**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:51
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:26

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:53:57**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:45:51
User entered '20 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:26

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 21:53:57**

[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 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:06
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:39

**US3042241**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 21:53:57**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:28:26
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:46:06
User entered '20 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:31:39

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 21:53:57**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:12:37
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:47:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	07 Oct 2020 18:24:14
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	19 Aug 2020 21:23:05
	(b) (4)	

US3042241

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 21:53:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
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)	14 Dec 2020 20:38:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:38:44
Data point term sent to Coder	System	14 Dec 2020 20:37:54
User entered 'WORSENING DEPRESSION'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07



**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '30 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 20:37:07



US3042241

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 21:53:57

Severity

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 10:29:02
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' answered with 'Grade per PT' (Site from DM).	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 15:55:53
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 06:19:44
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Dec 2020 22:19:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Dec 2020 22:19:57
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	24 Dec 2020 22:19:57
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:37:07
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07



**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 21:53:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Dec 2020 22:19:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Dec 2020 22:19:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	24 Dec 2020 22:19:57
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:37:07
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

US3042241

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 21:53:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Dec 2020 18:52:40
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Dec 2020 22:19:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Dec 2020 22:19:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	24 Dec 2020 22:19:57
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:37:07
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07



**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 20:37:07

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:29
User entered	System	06 Jan 2021 18:45:24
'USA-US052-2021-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	06 Jan 2021 18:45:24



US3042241

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:53:57

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:33:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:33:29
Data point term sent to Coder	System	05 Jan 2021 17:33:04
User entered 'SYMPTOMATIC COVID-19'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:53:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'PV Query: As event is reported as starting on 20 Dec 2020, please provide the subject's symptoms that he experienced on start date.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 19:36:21
Query 'PV Query: As event is reported as starting on 20 Dec 2020, please provide the subject's symptoms that he experienced on start date.' answered with 'symptoms experienced as unknown' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 20:06:48
User opened query 'PV Query: As event is reported as starting on 20 Dec 2020, please provide the subject's symptoms that he experienced on start date.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:16:47
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	05 Jan 2021 17:33:15
User entered '20 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:33:15
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	05 Jan 2021 17:32:32
User entered '20 Dec 2021'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 15:57:03
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:53:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'PV Query: Please consider adding symptoms for the dates 19 Jan 2021 and 20 Jan 2021 when event ended.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 19:36:29
Query 'PV Query: Please consider adding symptoms for the dates 19 Jan 2021 and 20 Jan 2021 when event ended.' answered with 'subject did not have symptoms that day' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 20:07:07
User opened query 'PV Query: Please consider adding symptoms for the dates 19 Jan 2021 and 20 Jan 2021 when event ended.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:18:04
User entered '20 Jan 2021' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 15:57:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	17 Apr 2021 14:01:34
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:21:47
User entered empty.	System	05 Jan 2021 17:32:32

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:53:57

Severity

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'PV Query: Please provide the event severity.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 18:19:12
Query 'PV Query: Please provide the event severity.' answered with 'severity provided' (Site from Safety).	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 15:57:17
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 15:57:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 15:57:03
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 15:57:03
User opened query 'PV Query: Please provide the event severity.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:22:10
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:32:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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Folder: Adverse Events

Form: Adverse Events (8)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 14:25:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 14:25:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	13 Jan 2021 14:25:18
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:32:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32



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Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:53:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 14:25:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 14:25:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	13 Jan 2021 14:25:18
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Jan 2021 17:32:32
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:53:57

None

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #7 and 8 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 15:52:28
Query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #7 and 8 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Feb 2021 23:39:25
User entered '0' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Feb 2021 23:39:19
User opened query 'Per DM CLR: Other Action Taken = None, however there were Concomitant Medication #7 and 8 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 06:19:55
User entered '1'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '1' reason for change: Data Entry Error	Rylea Gulick (b) (4)	02 Feb 2021 23:39:19
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 15:57:03
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 19:27:01
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'WILL BE INPUT WHEN AVAILABLE.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	02 Feb 2021 23:39:43
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:21:32
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:53:57

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 19:36:45
User closed query 'PV Query: There are some treatment medications for pneumonia. Please confirm if this is pneumonia associated with event, symptomatic COVID 19, and if so please consider updating event to COVID-19 pneumonia.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 19:36:39
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'there are no results to send.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 20:08:33
Query 'PV Query: There are some treatment medications for pneumonia. Please confirm if this is pneumonia associated with event, symptomatic COVID 19, and if so please consider updating event to COVID-19 pneumonia.' answered with 'unknown if pneumonia is connected to covid-19' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 20:07:59
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:17:34



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Folder: Adverse Events

Form: Adverse Events (8)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: There are some treatment medications for pneumonia. Please confirm if this is pneumonia associated with event, symptomatic COVID 19, and if so please consider updating event to COVID-19 pneumonia.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:17:06
User closed query 'PV Query: The start date of the event is 20 Dec 2020. Did the subject report any symptoms on that day? If yes, please add to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 19:27:16
Query 'PV Query: The start date of the event is 20 Dec 2020. Did the subject report any symptoms on that day? If yes, please add to the COVID-19 assessment symptom log in EDC.' answered with 'START DATE FOR 20DEC2020 IS ALREADY IN SYMPTOM LOG' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	02 Feb 2021 23:40:06
User opened query 'PV Query: The start date of the event is 20 Dec 2020. Did the subject report any symptoms on that day? If yes, please add to the COVID-19 assessment symptom log in EDC.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:20:43
User entered empty.	Rylea Gulick (b) (4) (b) (4)	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Jan 2021 17:32:32

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 18:03:56

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:53:57

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:23:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:23:42
Data point term sent to Coder	System	06 Jan 2021 18:22:59
User entered 'PNEUMONIA'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30



**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '06 Jan 2021'	Rylea Gulick (b) (4)	06 Jan 2021 18:22:30
	(b) (4)	

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User entered empty.	(b) (4), (b) (6) System	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Jan 2021 16:36:36
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	06 Jan 2021 18:22:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:53:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
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	20 Jan 2021 16:36:44
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	20 Jan 2021 16:36:44
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	20 Jan 2021 16:36:36
User entered '13 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:36:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User entered empty.	(b) (4), (b) (6) System	06 Jan 2021 18:22:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:53:57

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 15:57:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 15:57:53
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 15:57:53
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 18:22:30
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30



**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4)	06 Jan 2021 18:22:30
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4)	06 Jan 2021 18:22:30
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4)	06 Jan 2021 18:22:30
	(b) (4)	



**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4)	06 Jan 2021 18:22:30
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:53:57

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 15:57:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 15:57:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 15:57:53
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 18:22:30
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:53:57

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 15:57:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 15:57:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	02 Mar 2021 15:57:53
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 18:22:30
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Jan 2021 16:36:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[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 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:48:49
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User entered '0'	(b) (4), (b) (6) System	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:03:56
User entered '1'	(b) (4), (b) (6) System	06 Jan 2021 18:22:30

**US3042241**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:53:57**

[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 18:03:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:53:57

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:12:37
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
User closed query 'Per ETRTR: Medication for COVID-19 Symptoms is found within this folder. Please go to COVID-19 AE page and tick on "Concomitant Medications" Action taken, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:49:53
Query 'Per ETRTR: Medication for COVID-19 Symptoms is found within this folder. Please go to COVID-19 AE page and tick on "Concomitant Medications" Action taken, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Feb 2021 23:40:30
User opened query 'Per ETRTR: Medication for COVID-19 Symptoms is found within this folder. Please go to COVID-19 AE page and tick on "Concomitant Medications" Action taken, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 21:11:06
Query 'Per ETRTR: Medication for COVID-19 Symptoms is found within this folder. Please go to COVID-19 AE page and tick on "Concomitant Medications" Action taken, tahaks.' canceled (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 21:10:41
User opened query 'Per ETRTR: Medication for COVID-19 Symptoms is found within this folder. Please go to COVID-19 AE page and tick on "Concomitant Medications" Action taken, tahaks.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 21:10:32
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:23:06
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:16:44



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
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)	19 Aug 2020 21:19:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:19:07
Data point term sent to Coder	System	19 Aug 2020 21:18:18
User entered 'BUPROPION'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'DEPRESSION'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '300'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Aug 2020 07:19:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 21:17:52
User entered 'UN UNK 2016'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:53:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	17 Mar 2021 15:12:50
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	19 Aug 2020 21:17:52
	(b) (4)	

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '26 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:12:50
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:17:52

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User entered '1'	(b) (4), (b) (6) System	19 Aug 2020 21:17:52



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User entered '1'	(b) (4), (b) (6) System	19 Aug 2020 21:17:52

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:57:51
User entered '804 (804)'	(b) (4), (b) (6) System	19 Aug 2020 21:17:52

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: ATOMOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: STRATTERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:22:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:22:10
Data point term sent to Coder User entered 'STRATTERA'	System Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:22 19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'ATTENTION DEFICIT DISORDER'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '60'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Aug 2020 07:19:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 21:18:27
User entered 'UN UNK 2019'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:13:00
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '26 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:13:00
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27



US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:53:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User entered '1'	(b) (4), (b) (6) System	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User entered '1'	(b) (4), (b) (6) System	19 Aug 2020 21:18:27

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:03
User entered '804 (804)'	(b) (4), (b) (6) System	19 Aug 2020 21:18:27

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:21:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:21:12
Data point term sent to Coder	System	19 Aug 2020 21:20:23
User entered 'MIRENA IUD'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'CONTRACEPTION'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '52'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'other (OTHER)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Q5YEARS'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User closed query 'Per CDM: Please review "Other Route" as there is an available option for "Vaginal" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and update as appropriate' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:52:50
Query 'Per CDM: Please review "Other Route" as there is an available option for "Vaginal" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and update as appropriate' answered with 'THIS IS AN INTRAUTERINE DEVICE' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:37:08
User opened query 'Per CDM: Please review "Other Route" as there is an available option for "Vaginal" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and update as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:09:56
User entered 'Other (OTHER)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'INTRAUTERINE'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:53:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Aug 2020 07:20:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 21:19:28
User entered 'UN Nov 2016'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:19:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:19:28

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: GUAIFENESIN;PARACETAMOL;PHENYLEPHRI NE HYDROCHLORIDE, PRODUCTSYNONYM: TYLENOL SINUS SEVERE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:14:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:14:37
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:04:58 07 Nov 2020 15:04:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: GUAIFENESIN;PARACETAMOL;PHENYLEPHRI NE HYDROCHLORIDE, PRODUCTSYNONYM: TYLENOL SINUS SEVERE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:37:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:37:32
Data point term sent to Coder	System	04 Nov 2020 21:24:57
User closed query 'For coding purposes, references indicate different formulations for TYLENOL SINUS. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	04 Nov 2020 21:24:56

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:57

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'For coding purposes, references indicate different formulations for TYLENOL SINUS. 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)	04 Nov 2020 21:24:56
User entered 'TYLENOL SINUS [ACETAMINOPHEN, GUAIFENESIN, PHENYLEPHRINE]' reason for change: Data Entry Error	Rylea Gulick (b) (4)	04 Nov 2020 21:24:51
User opened query 'For coding purposes, references indicate different formulations for TYLENOL SINUS. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4)	30 Oct 2020 20:28:56
Data point term sent to Coder	System	14 Oct 2020 14:38:39
User entered 'TYLENOL SINUS' reason for change: Data Entry Error	Rylea Gulick (b) (4)	14 Oct 2020 14:38:22
User entered 'TYLENOL'	Rylea Gulick (b) (4)	14 Oct 2020 14:38:11



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
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) (b) (4), (b) (6)	13 Jan 2021 06:15:19
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
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 'AE WAS PRESENT, HOWEVER, IT WAS REMOVED AS IT WAS NOT A TRUE AE.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	07 Dec 2020 16:59:05
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)	04 Dec 2020 03:37:22
User entered 'SORE THROAT' reason for change:	Rylea Gulick (b) (4)	07 Nov 2020 15:04:27
Data Entry Error	(b) (4)	
User entered 'SOLICITED SYMPTOM-SORE THROAT'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 5/325/200)' canceled (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 03:45:01
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 5/325/200)' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 03:37:31
User entered '325'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '27 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '05 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:53:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
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 13:36:27
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)	07 Nov 2020 15:04:34
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:04:27
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)	06 Nov 2020 11:52:30
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Oct 2020 14:38:11

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 14:38:11

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 14:38:11



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:59:47
User entered empty.	(b) (4), (b) (6) System	14 Oct 2020 14:38:11

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:53:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:48:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:48:39
Data point term sent to Coder	System	09 Nov 2020 21:47:27
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'INFLUENZA PREVENTION'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0.5'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mL (mL)'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'once (ONCE)'	(b) (4), (b) (6)	09 Nov 2020 21:47:10



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '25 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '25 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 21:47:10



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User entered empty.	(b) (4), (b) (6) System	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User entered empty.	(b) (4), (b) (6) System	09 Nov 2020 21:47:10

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:07
User entered empty.	(b) (4), (b) (6) System	09 Nov 2020 21:47:10

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
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)	14 Dec 2020 20:39:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:39:44
Data point term sent to Coder	System	14 Dec 2020 20:38:56
User entered 'DESVENLAFAXINE'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'WORSENING DEPRESSION'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 10:46:57
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'THIS IS THE DOSE SUBJECT REPORTS TAKING' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:52
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:09:46
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '45'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20



US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '07 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:53:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:13:37
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '26 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:13:37
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User entered '1'	(b) (4), (b) (6) System	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User entered '1'	(b) (4), (b) (6) System	14 Dec 2020 20:38:20

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:19
User entered '804 (804)'	(b) (4), (b) (6) System	14 Dec 2020 20:38:20

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:34
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: PHENYLEPHRINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:47:51
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 Dec 2020 18:47:51
Data point term sent to Coder	System	23 Dec 2020 18:40:20
User entered 'Phenylephrine HCL'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:35
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:37
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'COVID like symptoms: Nasal Congestion'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '10'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:43
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mg (mg)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:45
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:46
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'as needed (PRN)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:48
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:50
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Oral (ORAL)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:52
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '20 Dec 2020'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:56
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
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)	01 Apr 2021 02:07:25
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 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:13
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:09
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:09
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)	10 Mar 2021 12:09:01
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:25:58
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:53:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:09
User entered '20 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:09
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:26:00
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:01
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 18:39:51

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:00:54
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 18:39:51

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:38
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:43:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:43:46
Data point term sent to Coder User entered 'Tylenol'	System Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:24 23 Dec 2020 18:42:14



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:40
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:41
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'COVID like symptoms: Muscle Aches'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:43
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '500'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:48
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mg (mg)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:50
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:56
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'as needed (PRN)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:53
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:54
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Oral (ORAL)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:01
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:03
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '20 Dec 2020'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:05
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
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)	01 Apr 2021 02:07:34
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 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:27
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:23
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:23
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)	10 Mar 2021 12:09:11
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:25:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:23
User entered '20 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	30 Mar 2021 18:59:23
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:25:08
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:53:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:25:09
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 18:42:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 18:42:19
User entered 'No (N)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:19
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 18:42:14
User entered empty.	Jamie Thompson (b) (4) (b) (4)	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 18:42:14

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 18:42:14



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:01:22
User entered empty.	(b) (4), (b) (6) System	23 Dec 2020 18:42:14

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:53:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:25:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:25:42
Data point term sent to Coder	System	06 Jan 2021 18:25:00
User entered 'AZITHROMYCIN'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'PNEUMONIA'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '500'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:53:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:53:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22



US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:53:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '06 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:53:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
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 Mar 2021 17:38:41
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 'ENTRY UPDATED ' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:14:12
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:14:04
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)	15 Feb 2021 01:25:41
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '12 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:14:04
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:22



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User entered '1'	(b) (4), (b) (6) System	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User entered '1'	(b) (4), (b) (6) System	06 Jan 2021 18:24:22

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:02:32
User entered '804 (804)'	(b) (4), (b) (6) System	06 Jan 2021 18:24:22

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:53:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
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: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:25:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:25:43
Data point term sent to Coder	System	06 Jan 2021 18:25:00
User entered 'PREDNISONE'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'PNEUMONIA'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '10'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:53:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45



US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:53:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:53:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:53:57

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:53:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '06 Jan 2021'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered '0'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:53:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
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 Mar 2021 17:38:56
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 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:14:50
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:14:21
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)	15 Feb 2021 01:25:50
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '12 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:14:21
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered empty.	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
DataPoint Un-verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:33
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 19:24:17
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User entered '1'	(b) (4), (b) (6) System	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User entered '1'	(b) (4), (b) (6) System	06 Jan 2021 18:24:45

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:01
User entered '804 (804)'	(b) (4), (b) (6) System	06 Jan 2021 18:24:45

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:53:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 21:58:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 21:58:06
Data point term sent to Coder	System	13 Jan 2021 21:57:20
User entered 'SYMBICORT'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'PNEUMONIA'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28



US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:53:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 80/4.5).' ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 01:32:09
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 80/4.5).' ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:06:34
User entered '80/4.5' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Mar 2021 19:06:28
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 80/4.5).' ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:23:47
User entered '80'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'ug (ug)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'as needed (PRN)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '12 Jan 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:53:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
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 Mar 2021 17:39:05
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 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:07
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:01
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)	15 Feb 2021 01:25:59
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '20 Jan 2021' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:01
User entered empty.	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 21:56:28

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:03:30
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 21:56:28

US3042241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 21:53:57

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:16:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 15:16:49
Data point term sent to Coder	System	17 Mar 2021 15:16:21
User entered 'ADDERALL XR'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'ATTENTION DEFICIT DISORDER'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '35'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '13 Feb 2021'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered '0'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:51:36
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 15:15:36



**US3042241**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 21:53:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 15:15:36

**US3042241**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 21:53:57**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:40:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:52:08
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	19 Aug 2020 21:22:59

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'USA-US052-2021-MRNA-1273-P301000002'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'David'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Meagan'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'Enszt'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Miller'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:22
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:17:09
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:47:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:42:05
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
User closed query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 16:53:42
Query 'Please add address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:55
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '4208 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User opened query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:05:20
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '330 dakota dunes suite400'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'SLOAN' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'North sioux'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:48
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'IA'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:18:00
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '57049'	System	06 Jan 2021 18:45:24



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 19:28:46
User entered 'US'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 19:39:04
User entered '4'	System	03 Mar 2021 18:22:36
User entered '3'	System	12 Feb 2021 14:24:34
User entered '2'	System	10 Feb 2021 19:28:16
User entered '1'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'USA-US052-2021-MRNA-1273-P301000002'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'David'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Meagan'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'Enszt'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Miller'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:22
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:17:09
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:47:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:42:05
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
User closed query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 16:53:42
Query 'Please add address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:55
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '4208 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User opened query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:05:20
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '330 dakota dunes suite400'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'SLOAN' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'North sioux'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:48
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'IA'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:18:00
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '57049'	System	06 Jan 2021 18:45:24



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 19:28:46
User entered 'US'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 19:39:04
User entered '4'	System	03 Mar 2021 18:22:36
User entered '3'	System	12 Feb 2021 14:24:34
User entered '2'	System	10 Feb 2021 19:28:16
User entered '1'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
User entered '06/Jan/2021 18:45'	System	06 Jan 2021 18:45:52

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:53:57

**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 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 19:28:46
User entered 'I'	(b) (4), (b) (6)	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'USA-US052-2021-MRNA-1273-P301000002'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'David'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Meagan'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'Enszt'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Miller'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:22
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:17:09
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:47:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:42:05
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
User closed query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 16:53:42
Query 'Please add address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:55
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '4208 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User opened query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:05:20
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '330 dakota dunes suite400'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'SLOAN' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'North sioux'	System	06 Jan 2021 18:45:24



US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:48
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'IA'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:18:00
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '57049'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 19:28:46
User entered 'US'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 19:39:04
User entered '4'	System	03 Mar 2021 18:22:36
User entered '3'	System	12 Feb 2021 14:24:34
User entered '2'	System	10 Feb 2021 19:28:16
User entered '1'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
User entered '10/Feb/2021 14:28'	System	10 Feb 2021 19:28:16

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:53:57

**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 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 19:28:46
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 19:28:16

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'USA-US052-2021-MRNA-1273-P301000002'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'David'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Meagan'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'Enszt'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Miller'	System	06 Jan 2021 18:45:24



US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:22
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:17:09
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:47:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:42:05
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
User closed query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 16:53:42
Query 'Please add address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:55
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '4208 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User opened query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:05:20
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '330 dakota dunes suite400'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'SLOAN' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'North sioux'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:48
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'IA'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:18:00
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '57049'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 19:28:46
User entered 'US'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 19:39:04
User entered '4'	System	03 Mar 2021 18:22:36
User entered '3'	System	12 Feb 2021 14:24:34
User entered '2'	System	10 Feb 2021 19:28:16
User entered '1'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
User entered '12/Feb/2021 09:24'	System	12 Feb 2021 14:24:34

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:53:57

**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 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 14:24:38
User entered 'I'	(b) (4), (b) (6)	12 Feb 2021 14:24:34



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'USA-US052-2021-MRNA-1273-P301000002'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'David'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Meagan'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'Enszt'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Miller'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:22
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:17:09
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:47:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:42:05
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
User closed query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 16:53:42
Query 'Please add address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:55
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '4208 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User opened query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:05:20
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '330 dakota dunes suite400'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'SLOAN' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'North sioux'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:48
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'IA'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:18:00
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '57049'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 19:28:46
User entered 'US'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 19:39:04
User entered '4'	System	03 Mar 2021 18:22:36
User entered '3'	System	12 Feb 2021 14:24:34
User entered '2'	System	10 Feb 2021 19:28:16
User entered '1'	System	06 Jan 2021 18:45:52



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
User entered '03/Mar/2021 13:22'	System	03 Mar 2021 18:22:36

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:53:57

**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 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 18:22:36

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'USA-US052-2021-MRNA-1273-P301000002'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'No (N)'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'David'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Meagan'	System	06 Jan 2021 18:45:24

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered 'Enszt'	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'Miller'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:22
User closed query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:17:09
Query 'Please enter this again, hopefully glitch is fixed, thanks' answered with 'entry updated' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:47:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
User opened query 'Please enter this again, hopefully glitch is fixed, thanks' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:42:05
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
User closed query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 16:53:42
Query 'Please add address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:55
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '4208 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User opened query 'Please add address, thanks' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:05:20
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '330 dakota dunes suite400'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:34
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'SLOAN' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'North sioux'	System	06 Jan 2021 18:45:24

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Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:17:48
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered 'IA'	System	06 Jan 2021 18:45:24

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 21:53:57

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:18:00
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Apr 2021 14:46:54
Un-reviewed for Safety.	System	09 Apr 2021 19:39:04
DataPoint Un-verified.	System	09 Apr 2021 19:39:04
User entered empty.	System	09 Apr 2021 19:39:04
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:38:41
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 16:53:48
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	11 Mar 2021 17:04:33
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 18:22:48
Un-reviewed for Safety.	System	03 Mar 2021 18:22:36
User entered empty.	System	03 Mar 2021 18:22:36
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 18:45:44
User entered '57049'	System	06 Jan 2021 18:45:24



**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:53:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 19:28:46
User entered 'US'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:53:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	09 Apr 2021 19:39:04
User entered '4'	System	03 Mar 2021 18:22:36
User entered '3'	System	12 Feb 2021 14:24:34
User entered '2'	System	10 Feb 2021 19:28:16
User entered '1'	System	06 Jan 2021 18:45:52

**US3042241**

**Folder: SAE USA-US052-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 11 Aug 2021 21:53:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:05:50
User entered '09/Apr/2021 15:39'	System	09 Apr 2021 19:39:04

US3042241

Folder: SAE USA-US052-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 21:53:57

**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 15:41:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:05:50
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 19:39:04