

US3402153 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:42:09

All time stamps listed in this document are displayed in GMT

US3402153

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

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[Participant ID](#)

US3402153

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

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US3402153

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 16:54:30

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

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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) 15 Feb 2021 16:54:30

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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) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	10 APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Condition	RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN DEC 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2008
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2008
Start Year (derived)	2008
Stop Month and Year (derived)	DEC 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:55 (24 HR)
Vital Signs Date and Time (derived)	1 AUG 2020 13:55
Height ( <i>xxx.x</i> )	175 cm
Weight ( <i>xxx.x</i> )	99.5 kg
BMI ( <i>xxx.x</i> )	32.48980 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) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:54:30

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify** (b) (6)

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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) 15 Feb 2021 16:54:30

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

What was the date of randomization? (dd MMM yyyy) 01 AUG 2020

What was the participant's randomization number? 142575

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

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) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

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)	1 AUG 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	1 AUG 2020 13:55
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

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)	1 AUG 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	1 AUG 2020 15:05
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

1 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

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) 1 AUG 2020

What was the treatment time? (00:00-23:59) 14:28 (24 HR)

Treatment Date and Time (derived) 1 AUG 2020 14:28

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) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 AUG 2020

Collection time (00:00-23:59)

14:22 (24 HR)

Collection date and time (derived)

1 AUG 2020 14:22

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Collection date (dd MMM yyyy)			1 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:25	1 AUG 2020 14:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

01 AUG 2020 15:04

PC Open Date & Time

01 AUG 2020 14:48

PC Close Date & Time

01 AUG 2020 17:18

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 18:19

PC Open Date & Time

01 AUG 2020 18:13

PC Close Date & Time

02 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 18:03

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**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

03 AUG 2020 18:05

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 18:02

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**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

98.2 °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

05 AUG 2020 17:53

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

06 AUG 2020 18:03

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**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

98.3 °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

07 AUG 2020 18:01

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 15:04

PC Open Date & Time

01 AUG 2020 14:48

PC Close Date & Time

01 AUG 2020 17:18

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**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

01 AUG 2020 18:20

PC Open Date & Time

01 AUG 2020 18:13

PC Close Date & Time

02 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**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

02 AUG 2020 18:03

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59



US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**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

03 AUG 2020 18:05

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**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

04 AUG 2020 18:03

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**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

05 AUG 2020 17:54

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**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

06 AUG 2020 18:03

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**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

07 AUG 2020 18:02

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**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 ☐

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 15:05
PC Open Date & Time	01 AUG 2020 14:48
PC Close Date & Time	01 AUG 2020 17:18

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**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 ☐



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 18:20
PC Open Date & Time	01 AUG 2020 18:13
PC Close Date & Time	02 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 3240

EAB) (1725)

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 18:04
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 3240

EAB) (1725)

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 18:06
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**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 ☒

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 18:03
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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 ☒



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 17:54
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 18:04
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**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 ☒

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:02
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3402153

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

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)	1 SEP 2020
Time of assessment (00:00-23:59)	15:52 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 15:52
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)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	17:10 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 17:10
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3402153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 16:38 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 16:38

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



US3402153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	16:11 (24 HR)
Collection date and time (derived)	1 SEP 2020 16:11

US3402153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Collection date (dd MMM yyyy)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:14	1 SEP 2020 16:14
Nasopharyngeal Swab 2	No		

US3402153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

01 SEP 2020 17:16

PC Open Date & Time

01 SEP 2020 16:58

PC Close Date & Time

01 SEP 2020 19:28

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**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 98.3 °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	01 SEP 2020 21:04
PC Open Date & Time	01 SEP 2020 20:23
PC Close Date & Time	02 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**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

98.1 °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

02 SEP 2020 18:18

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 17:31

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**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

98.3 °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

04 SEP 2020 18:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**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

98.5 °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

05 SEP 2020 17:32

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

06 SEP 2020 18:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 7

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

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

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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

07 SEP 2020 19:14

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 17:17

PC Open Date & Time

01 SEP 2020 16:58

PC Close Date & Time

01 SEP 2020 19:28

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**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

01 SEP 2020 21:05

PC Open Date & Time

01 SEP 2020 20:23

PC Close Date & Time

02 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**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

02 SEP 2020 18:19

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**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

03 SEP 2020 17:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**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

04 SEP 2020 18:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**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

05 SEP 2020 17:32

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**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

06 SEP 2020 18:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**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

07 SEP 2020 19:14

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**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 ☐

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 17:17
PC Open Date & Time	01 SEP 2020 16:58
PC Close Date & Time	01 SEP 2020 19:28

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**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 ☐

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 21:05
PC Open Date & Time	01 SEP 2020 20:23
PC Close Date & Time	02 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 18:19
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 17:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 18:37
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**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 ☒

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

		Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 17:33	
PC Open Date & Time	05 SEP 2020 12:00	
PC Close Date & Time	06 SEP 2020 11:59	

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 19:15
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3402153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3402153

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:54:30

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	15:08 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 15:08
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	92 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

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.*

US3402153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 OCT 2020

Collection time (00:00-23:59)

15:15 (24 HR)

Collection date and time (derived)

2 OCT 2020 15:15

US3402153

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:54:31

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

05 OCT 2020 23:59



US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

08 OCT 2020 22:48:08

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

15 OCT 2020 19:51:21

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 19:30:22
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 21:07:27

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59



US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 16:37:01
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

26 NOV 2020 19:00:35

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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	03 DEC 2020 19:37:59
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 19:01:23

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

18 DEC 2020 11:22:49

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

24 DEC 2020 19:04:37

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59



US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

07 JAN 2021 18:56:22

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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)	True
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 JAN 2021 13:25:31
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

20 JAN 2021 21:12:50

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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	27 JAN 2021 17:20:42
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 16:38:37

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 17:12:41
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 13:02:12

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59



US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

24 FEB 2021 16:47:16

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

03 MAR 2021 12:28:26

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 16:48:03

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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 <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 type="radio"/> Yes <input checked="" 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)	True
Chills	True
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	15 MAR 2021 15:20:12
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 15:34:06
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

30 MAR 2021 18:16:13

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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

05 APR 2021 14:22:36

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 16:27:10

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59



US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 16:49:59

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 14:37:23

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 08:33:14

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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="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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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°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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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31 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUN 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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°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 ☐

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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28 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUL 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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05 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUL 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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 ☐ 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 ☐

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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="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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

26 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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 <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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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02 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Close Date & Time](#)

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27 AUG 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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 ☐

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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06 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 SEP 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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04 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 OCT 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59
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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Close Date & Time](#)

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05 NOV 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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06 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 DEC 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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20 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 DEC 2021 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2021 23:59
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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Close Date & Time](#)

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21 JAN 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JAN 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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 ☐



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 565

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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°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 ☐

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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21 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 FEB 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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 <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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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14 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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21 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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28 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 APR 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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04 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 APR 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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 ☐ 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 ☐

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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 ☐  
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 ☐

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**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 ☐ 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 ☐

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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04 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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22 JUL 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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08 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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19 AUG 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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26 AUG 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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02 SEP 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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12 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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"/>

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2022 23:59

US3402153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

**US3402153**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 11 Aug 2021 22:42:09**

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		03 MAR 2021 15:04:37



US3402153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:17:15

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:17:15

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3402153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

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

Visit date (dd MMM yyyy)	09 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3402153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

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) \_\_\_\_\_

US3402153

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

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.*

US3402153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 MAR 2021

Collection time (00:00-23:59)

15:17 (24 HR)

Collection date and time (derived)

09 MAR 2021 15:17

US3402153

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 22:58:09

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3402153

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 22:58:09

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3402153**

**Folder: Safety Call Day 299 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

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*

**US3402153**

**Folder: Safety Call Day 299 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

Date of Contact	13 JAN 2021
Time of Contact	12:00
Date and Time of Contact (derived)	13 JAN 2021 12:00
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>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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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US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>



US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	37.9 C	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	99.1 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 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	97 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	99.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	96 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 type="radio"/>
	Mild	<input checked="" 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 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	94 %	
O2 Saturation Units	%	
Temperature	99.8 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 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 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 JAN 2021	
Assessment Not Done	False	
O2 Saturation	89 %	
O2 Saturation Units	%	
Temperature	100.2 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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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	100.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	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 type="radio"/>
	Mild	<input checked="" 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 (11)

Data signed: (b) (4) 26 Apr 2021 01:48:42

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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 type="radio"/>
	Mild	<input checked="" 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 (12)

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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 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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	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.7 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 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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	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input 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 (12)

Data signed: (b) (4) 26 Apr 2021 01:48:42

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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 (13)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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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Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 JAN 2021	
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 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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	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input 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 13 Jan 2021

Form: Symptom Log (13)

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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 (14)

Data signed: (b) (4) 26 Apr 2021 01:48:42

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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 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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Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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

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

O2 Saturation	93 %
---------------	------

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 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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Data signed: (b) (4) 26 Apr 2021 01:48:42

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

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Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 (15)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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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Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 11 Aug 2021 22:42:09

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

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Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 (16)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	92 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 13 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 13 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
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 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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Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
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 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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐



US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.8 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"/>
PRODUCTION RELEASE (v12.003		409 of 3240
EAB) (1725)		

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>

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Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	1 FEB 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
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 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		413 of 3240
EAB) (1725)		

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 13 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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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Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	2 FEB 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.3 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 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 13 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	3 FEB 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐



US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	4 FEB 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		425 of 3240
EAB) (1725)		

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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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US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	5 FEB 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
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 13 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 13 Jan 2021

Form: Symptom Log (27)

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Generated On: 11 Aug 2021 22:42:09

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 13 Jan 2021

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	6 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		433 of 3240
EAB) (1725)		

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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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US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	7 FEB 2021	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐



US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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"/>

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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	8 FEB 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 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 13 Jan 2021

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

	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 13 Jan 2021

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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 ☐

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

Date of Visit	13 JAN 2021
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	13 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" 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

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

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 \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

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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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

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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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

Hepatic Dysfunction? Yes ☐  
No ☐

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

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

Start Date

End Date



US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 01:48:42

Generated On: 11 Aug 2021 22:42:09

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

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**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 26 Apr 2021 01:49:05

**Generated On: 11 Aug 2021 22:42:09**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 JAN 2021
Day 5	Yes	16 JAN 2021
Day 7	Yes	19 JAN 2021
Day 9	Yes	21 JAN 2021
Day 14	Yes	26 JAN 2021
Day 21	Yes	2 FEB 2021
Day 28	Yes	09 FEB 2021

US3402153

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

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

Visit date (dd MMM yyyy)	13 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3402153

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 JAN 2021
Time of assessment ( <i>00:00-23:59</i> )	12:13 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 12:13
Height ( <i>xxx.x</i> )	ND - Not Done
Weight ( <i>xxx.x</i> )	ND - Not Done
Temperature ( <i>xxx.x</i> )	37.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	96 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402153

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3402153

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 JAN 2021

US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 FEB 2021
Time of assessment (00:00-23:59)	14:23 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 14:23
Height (xxx.x)	177.7 cm
Weight (xxx.x)	202 lb
Temperature (xxx.x)	37.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3402153

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Apr 2021 01:48:41

Generated On: 11 Aug 2021 22:42:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

9 FEB 2021

US3402153

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

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

Visit date (dd MMM yyyy)	9 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3402153

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Date of updated informed consent ( <i>dd MMM yyyy</i> )	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	09 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3402153

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

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

US3402153

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 MAR 2021
Time of assessment (00:00-23:59)	15:36 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 15:36
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)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402153

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 MAR 2021
Time of assessment (00:00-23:59)	16:30 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 16:30
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3402153

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

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

9 MAR 2021

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

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US3402153

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

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 9 MAR 2021

What was the treatment time? (00:00-23:59) 15:55 (24 HR)

Treatment Date and Time (derived) 9 MAR 2021 15:55

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

US3402153

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00-23:59)	15:17 (24 HR)
Collection date and time (derived)	9 MAR 2021 15:17

US3402153

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00 - 23:59)	15:12
Collection Date and Time (derived)	9 MAR 2021 15:12

US3402153

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

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3402153

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

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)	5 APR 2021
Time of assessment (00:00-23:59)	14:54 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 14:54
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG



US3402153

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	5 APR 2021
Time of assessment (00:00-23:59)	15:46 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 15:46
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3402153

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 APR 2021

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

US3402153

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 5 APR 2021

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

Treatment Date and Time (derived) 5 APR 2021 15:15

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

US3402153

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:49:05

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402153

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402153

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 May 2021 22:58:09

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 May 2021 22:58:09

Generated On: 11 Aug 2021 22:42:09

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) \_\_\_\_\_



US3402153

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 May 2021 22:58:09

Generated On: 11 Aug 2021 22:42:09

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.*

US3402153

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 May 2021 22:58:09

Generated On: 11 Aug 2021 22:42:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 APR 2021

Collection time (00:00-23:59)

15:00 (24 HR)

Collection date and time (derived)

30 APR 2021 15:00

US3402153

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:36:22

Generated On: 11 Aug 2021 22:42:09

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3402153

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 22:58:09

Generated On: 11 Aug 2021 22:42:09

AEID	USA-US059-2021-MRNA-1273-P30 1000002
Adverse event	SARS 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)	10 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)	28 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 (1)

Data signed: (b) (4) 03 May 2021 22:58:09

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

---

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

Yes ☒

No ☐

---

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

---

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication OMEGA 3 FISH OIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication ZOLPIDEM

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication COLACE (DOCUSATE SODIUM)

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication VITAMIN B-12

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication JARDIENCE

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

	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)	10 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication NABUMETONE

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication BENAZEPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

	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 2010	
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"/>



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication LORATIDINE

Prophylaxis Yes ☐  
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

	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 2010	
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"/>

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication SARS COVID-19

Dose per administration 650

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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US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication ASA

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

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 ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Name of Medication BENZONATATE

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3402153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:27:49

Generated On: 11 Aug 2021 22:42:09

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 JAN 2021	CHEST XRAY	Adverse Event	

US3402153

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:42:09

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

US3402153

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:42:09

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 ☐



US3402153

Folder: SAE USA-US059-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

SAEID	USA-US059-2021-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3402153

Folder: SAE USA-US059-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

SAEID	USA-US059-2021-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/JAN/2021 19:26
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

US3402153

Folder: SAE USA-US059-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

SAEID	USA-US059-2021-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/FEB/2021 09:23
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

US3402153

Folder: SAE USA-US059-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 01:49:06

Generated On: 11 Aug 2021 22:42:09

SAEID	USA-US059-2021-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/APR/2021 09:33
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

US3402153 (Prod: Meridian Clinical Research, LLC)

**US3402153**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:42:09**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'US3402153'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:09:06

**US3402153**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 18:39:06

US3402153

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '01 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:09:07



US3402153

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Clinic (Clinic)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 18:39:06

**US3402153**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'SCRN'	System	01 Aug 2020 18:39:06

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:09:07

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '61'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'YEARS'	System	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '61'	System	01 Aug 2020 18:38:02

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Male (M)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34



**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'I'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34

**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34



**US3402153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:42:09**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:34

US3402153

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:09

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 18:38:02

**US3402153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Aug 2020'	System	01 Aug 2020 18:38:02

**US3402153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '2020'	System	01 Aug 2020 18:38:02

**US3402153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:42:09**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Amendment 1 (1)'	(b) (4) Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 18:38:02

**US3402153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 18:38:02

**US3402153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:42:09**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 18:38:02

**US3402153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:42:09**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 18:38:02



US3402153

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:09

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 18:38:02

**US3402153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:42:09**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:09:07

**US3402153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:42:09**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'I'	System	01 Aug 2020 18:38:08

**US3402153**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 18:38:08

US3402153

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:42:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:38:51

US3402153

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:40:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:40:14
Data point term sent to Coder	System	01 Aug 2020 19:39:51
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4)	01 Aug 2020 19:39:40

**US3402153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '10 Apr 2020'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:39:40

**US3402153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:39:40



**US3402153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:39:40

**US3402153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:39:40

**US3402153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:39:40

**US3402153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Apr 2020'	System	01 Aug 2020 19:39:40

**US3402153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '2020'	System	01 Aug 2020 19:39:40

**US3402153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:39:40

**US3402153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:39:40

US3402153

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:44:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:44:24
Data point term sent to Coder	System	01 Aug 2020 19:41:51
User entered 'OSTEOARTHRITIS: KNEES, HANDS, BACK'	Tarin Gordon (b) (4)	01 Aug 2020 19:41:26



**US3402153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'UN UNK 2000' reason for change:	(b) (4)	
Data Entry Error	Traci Hull (b) (4)	02 Aug 2020 19:12:41
User entered 'UN UNK 2008'	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:41:26
	(b) (4)	

**US3402153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:26

**US3402153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:26

**US3402153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:26

**US3402153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:26

**US3402153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Jan 2000'	System	02 Aug 2020 19:12:41
User entered 'Jan 2008'	System	01 Aug 2020 19:41:26

**US3402153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '2000'	System	02 Aug 2020 19:12:41
User entered '2008'	System	01 Aug 2020 19:41:26

**US3402153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:41:26



**US3402153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:41:26

US3402153

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:43:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:43:14
Data point term sent to Coder	System	01 Aug 2020 19:41:51
User entered 'HYPERTENSION'	Tarin Gordon (b) (4)	01 Aug 2020 19:41:39

**US3402153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'UN UNK 2010'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:39

**US3402153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:39

**US3402153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:39

**US3402153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4)	01 Aug 2020 19:41:39
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:39

**US3402153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Jan 2010'	System	01 Aug 2020 19:41:39



**US3402153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '2010'	System	01 Aug 2020 19:41:39

**US3402153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:41:39

**US3402153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:41:39

US3402153

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
Data point term sent to Coder	System	01 Aug 2020 19:42:52
User entered 'HYPERLIPIDEMIA'	Tarin Gordon (b) (4)	01 Aug 2020 19:41:52

**US3402153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'UN UNK 2015'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:52

**US3402153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:52

**US3402153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:52

**US3402153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:52



**US3402153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:41:52

**US3402153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Jan 2015'	System	01 Aug 2020 19:41:52

**US3402153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '2015'	System	01 Aug 2020 19:41:52

**US3402153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:41:52

**US3402153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:41:52

US3402153

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
Data point term sent to Coder	System	01 Aug 2020 19:42:52
User entered 'ENVIRONMENTAL ALLERGIES'	Tarin Gordon (b) (4)	01 Aug 2020 19:42:08

**US3402153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'UN UNK 1980'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:08

**US3402153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:08



**US3402153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:08

**US3402153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:08

**US3402153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:08

**US3402153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Jan 1980'	System	01 Aug 2020 19:42:08

**US3402153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '1980'	System	01 Aug 2020 19:42:08

**US3402153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:42:08

**US3402153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:42:08

US3402153

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
Data point term sent to Coder	System	01 Aug 2020 19:42:52
User entered 'INSOMNIA'	Tarin Gordon (b) (4)	01 Aug 2020 19:42:24



**US3402153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'UN UNK 2010'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:24

**US3402153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:24

**US3402153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:24

**US3402153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:24

**US3402153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:24

**US3402153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Jan 2010'	System	01 Aug 2020 19:42:24

**US3402153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '2010'	System	01 Aug 2020 19:42:24

**US3402153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:42:24



**US3402153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:42:24

US3402153

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User closed query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4)	12 Oct 2020 14:09:46
Query 'Per MM: Please update to reflect the etiology, if known. ' answered with 'PATIENT SUFFERS FROM MEDICATION INDUCED CONSTIPATION' (Site from DM).	(b) (4), (b) (6)	
	Tammy Kohn (b) (4)	07 Oct 2020 12:27:03
	(b) (4)	
User opened query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 07:51:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 19:42:52
User entered 'CONSTIPATION'	Tarin Gordon (b) (4)	01 Aug 2020 19:42:40
	(b) (4)	

**US3402153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'UN UNK 2013'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:40

**US3402153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:40

**US3402153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:40

**US3402153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:40

**US3402153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:42:40

**US3402153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Jan 2013'	System	01 Aug 2020 19:42:40



**US3402153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '2013'	System	01 Aug 2020 19:42:40

**US3402153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:42:40

**US3402153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	01 Aug 2020 19:42:40

US3402153

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:42:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 19:44:14
Data point term sent to Coder	System	01 Aug 2020 19:43:52
User entered 'RIGHT KNEE REPLACEMENT'	Tarin Gordon (b) (4)	01 Aug 2020 19:43:00

**US3402153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'UN Dec 2008'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:43:00

**US3402153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:43:00

**US3402153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:43:00

**US3402153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'UN Dec 2008'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:43:00



**US3402153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:43:00

**US3402153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Dec 2008'	System	01 Aug 2020 19:43:00

**US3402153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '2008'	System	01 Aug 2020 19:43:00

**US3402153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'Dec 2008'	System	01 Aug 2020 19:43:00

**US3402153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '2008'	System	01 Aug 2020 19:43:00

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:43:46

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:43:46

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '13:55'	(b) (4)	01 Aug 2020 19:43:46
	Tarin Gordon (b) (4)	
	(b) (4)	



**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '1 Aug 2020 13:55'	System	01 Aug 2020 19:43:46

US3402153

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '175' cm	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:43:46
DataPoint set to visible.	(b) (4)	
	System	01 Aug 2020 18:38:08

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '99.5' kg	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:43:46
DataPoint set to visible.	(b) (4)	
	System	01 Aug 2020 18:38:08

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
Amendment Manager: User entered '32.48980'	System	16 Sep 2020 23:40:32
User entered '32.5'	System	01 Aug 2020 19:43:46
DataPoint set to visible.	System	01 Aug 2020 18:38:08

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'kg/m2'	System	01 Aug 2020 19:43:46
DataPoint set to visible.	System	01 Aug 2020 18:38:08

US3402153

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:34:04
User entered '36.6' C	Tarin Gordon (b) (4)	01 Aug 2020 19:43:46
	(b) (4)	

US3402153

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:34:04
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	01 Aug 2020 19:43:46
	(b) (4)	

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:43:46



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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:34:04
User entered '86'	Tarin Gordon (b) (4)	01 Aug 2020 19:43:46
	(b) (4)	

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'bpm'	System	01 Aug 2020 19:43:46

US3402153

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:34:04
User entered '13'	Tarin Gordon (b) (4)	01 Aug 2020 19:43:46
	(b) (4)	

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'breaths/min'	System	01 Aug 2020 19:43:46

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:34:04
User entered '122'	Tarin Gordon (b) (4)	01 Aug 2020 19:43:46
	(b) (4)	

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'mmHg'	System	01 Aug 2020 19:43:46

US3402153

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:34:04
User entered '70'	Tarin Gordon (b) (4)	01 Aug 2020 19:43:46
	(b) (4)	

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'mmHg'	System	01 Aug 2020 19:43:46



**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47

**US3402153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47

**US3402153**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4)	01 Aug 2020 19:44:14
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 12:19:32
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 21:20:08
User entered '1 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:44:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

**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)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

**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)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:45:27



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Folder: Screening

Form: Risk of Exposure

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

**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)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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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)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

**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)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:42:09**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4)	01 Aug 2020 19:45:27
	Tarin Gordon (b) (4)	
	(b) (4)	



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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered (b) (6) ,	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:42:09**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4)	01 Aug 2020 19:45:27
	Tarin Gordon (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

**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)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

[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)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'I'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27

**US3402153**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:42:09**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:45:27



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:45:27
	(b) (4)	

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 18:38:54

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 18:38:54

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4)	01 Aug 2020 18:38:54

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'VISIT1'	System	01 Aug 2020 18:38:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '01 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:09:11

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:09

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:38:27
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:38:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 18:09:11
User entered '142575' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:09:11

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:09

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 18:09:11



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:09

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:46:02

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:09

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:46:02

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:42:09**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:46:02

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:42:09**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 19:46:02

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:42:09**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:46:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:33:45
User entered '175' cm	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:33:45
User entered '99.5' kg	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40
	(b) (4)	

US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:33:45
User entered '175' cm	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40
	(b) (4)	



US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:33:45
User entered '99.5' kg	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '13:55'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered '1 Aug 2020 13:55'	System	01 Aug 2020 19:47:40

US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '36.6' C	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:47:40



**US3402153**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '86'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'bpm'	System	01 Aug 2020 19:47:40

US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '13'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'breaths/min'	System	01 Aug 2020 19:47:40

US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '122'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'mmHg'	System	01 Aug 2020 19:47:40

US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '70'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'mmHg'	System	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:33:45
User entered '175' cm	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 15:33:45
User entered '99.5' kg	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

US3402153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
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) (b) (4), (b) (6)	17 Aug 2020 19:37:56
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN' (Site from System).	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:47:50
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		01 Aug 2020 19:47:40
User entered '15:05'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:47:40

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered '1 Aug 2020 15:05'	System	01 Aug 2020 19:47:40



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '36.3' C	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '80'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'bpm'	System	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '14'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'breaths/min'	System	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '122'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'mmHg'	System	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '72'	Tarin Gordon (b) (4)	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'mmHg'	System	01 Aug 2020 19:47:40

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 19:48:01

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Aug 2020'	Tarin Gordon (b) (4)	01 Aug 2020 19:48:01

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 18:38:40

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 18:38:40
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 18:38:40



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 18:38:40

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Aug 2020'	Tarin Gordon (b) (4)	01 Aug 2020 18:38:40

US3402153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '14:28'	Tarin Gordon (b) (4)	01 Aug 2020 18:38:40

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered '1 Aug 2020 14:28'	System	01 Aug 2020 18:38:40

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4)	01 Aug 2020 18:38:40

US3402153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'ONCE'	System	01 Aug 2020 18:38:40

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 18:38:40

US3402153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 19:48:29



US3402153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Aug 2020'	Tarin Gordon (b) (4)	01 Aug 2020 19:48:29

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '14:22'	Tarin Gordon (b) (4)	01 Aug 2020 19:48:29

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered '1 Aug 2020 14:22'	System	01 Aug 2020 19:48:29

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:42:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Aug 2020'	Tarin Gordon (b) (4)	01 Aug 2020 19:49:38

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:49:38

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:49:38

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:42:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '14:25'	Tarin Gordon (b) (4)	01 Aug 2020 19:49:38

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered '1 Aug 2020 14:25'	System	01 Aug 2020 19:49:38



**US3402153**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:49:38

US3402153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:42:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:49:38

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:42:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 19:49:38

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered empty.	System	01 Aug 2020 19:49:38

US3402153

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:42:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 19:50:02

**US3402153**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'I'	System	01 Aug 2020 19:50:02

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:03:23', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'cb1c17fe-2a0c-4db5-a739-88d46c2e2255'	System	01 Aug 2020 19:02:11
User entered 'Yes (Y)'	System	01 Aug 2020 19:02:11



US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:03:38', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'cb1c17fe-2a0c-4db5-a739-88d46c2e2255'	System	01 Aug 2020 19:02:11
User entered '97.3'	System	01 Aug 2020 19:02:11

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:03:55', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'cb1c17fe-2a0c-4db5-a739-88d46c2e2255'	System	01 Aug 2020 19:02:11
User entered 'No (N)'	System	01 Aug 2020 19:02:11

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:04:03', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'cb1c17fe-2a0c-4db5-a739-88d46c2e2255'	System	01 Aug 2020 19:02:11
User entered '01 Aug 2020 15:04'	System	01 Aug 2020 19:02:11

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Aug 2020 14:48'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Aug 2020 17:18'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:19:28', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '75e0270e-8f6c-4e14-bd0d-f1f9fb1d0844'	System	01 Aug 2020 22:17:56
User entered 'Yes (Y)'	System	01 Aug 2020 22:17:56

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:19:37', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '75e0270e-8f6c-4e14-bd0d-f1f9fb1d0844'	System	01 Aug 2020 22:17:56
User entered '97.9'	System	01 Aug 2020 22:17:56



US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:19:43', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '75e0270e-8f6c-4e14-bd0d-f1f9fb1d0844'	System	01 Aug 2020 22:17:56
User entered 'No (N)'	System	01 Aug 2020 22:17:56

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:19:48', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '75e0270e-8f6c-4e14-bd0d-f1f9fb1d0844'	System	01 Aug 2020 22:17:56
User entered '01 Aug 2020 18:19'	System	01 Aug 2020 22:17:56

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Aug 2020 18:13'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 2'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:02:54', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '58f58016-9e44-487d-9273-0955507d658b'	System	02 Aug 2020 22:01:23
User entered 'Yes (Y)'	System	02 Aug 2020 22:01:23

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:04', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '58f58016-9e44-487d-9273-0955507d658b'	System	02 Aug 2020 22:01:23
User entered '98.6'	System	02 Aug 2020 22:01:23

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:10', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '58f58016-9e44-487d-9273-0955507d658b'	System	02 Aug 2020 22:01:23
User entered 'No (N)'	System	02 Aug 2020 22:01:23



US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:15', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '58f58016-9e44-487d-9273-0955507d658b'	System	02 Aug 2020 22:01:23
User entered '02 Aug 2020 18:03'	System	02 Aug 2020 22:01:23

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 3'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:04:46', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'd4cfb03c-4058-40b1-9161-9898428f9d5a'	System	03 Aug 2020 22:03:10
User entered 'Yes (Y)'	System	03 Aug 2020 22:03:10

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:04:54', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'd4cfb03c-4058-40b1-9161-9898428f9d5a'	System	03 Aug 2020 22:03:10
User entered '98.4'	System	03 Aug 2020 22:03:10

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:04:59', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'd4cfb03c-4058-40b1-9161-9898428f9d5a'	System	03 Aug 2020 22:03:10
User entered 'No (N)'	System	03 Aug 2020 22:03:10

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:03', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'd4cfb03c-4058-40b1-9161-9898428f9d5a'	System	03 Aug 2020 22:03:10
User entered '03 Aug 2020 18:05'	System	03 Aug 2020 22:03:10



US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 4'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:02:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '291b1040-6031-486d-ba99-dae85e20d646'	System	04 Aug 2020 22:00:34
User entered 'Yes (Y)'	System	04 Aug 2020 22:00:34

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:02:17', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '291b1040-6031-486d-ba99-dae85e20d646'	System	04 Aug 2020 22:00:34
User entered '97.9'	System	04 Aug 2020 22:00:34

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:02:21', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '291b1040-6031-486d-ba99-dae85e20d646'	System	04 Aug 2020 22:00:34
User entered 'No (N)'	System	04 Aug 2020 22:00:34

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:02:26', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '291b1040-6031-486d-ba99-dae85e20d646'	System	04 Aug 2020 22:00:34
User entered '04 Aug 2020 18:02'	System	04 Aug 2020 22:00:34

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 18:38:40



US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 5'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:53:42', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '880e3822-4b82-4bc0-8ddb-4bddd2c4bb32'	System	05 Aug 2020 21:52:03
User entered 'Yes (Y)'	System	05 Aug 2020 21:52:03

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:53:48', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '880e3822-4b82-4bc0-8ddb-4bddd2c4bb32'	System	05 Aug 2020 21:52:03
User entered '98.2'	System	05 Aug 2020 21:52:03

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:53:53', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '880e3822-4b82-4bc0-8ddb-4bddd2c4bb32'	System	05 Aug 2020 21:52:03
User entered 'No (N)'	System	05 Aug 2020 21:52:03

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:53:56', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '880e3822-4b82-4bc0-8ddb-4bddd2c4bb32'	System	05 Aug 2020 21:52:03
User entered '05 Aug 2020 17:53'	System	05 Aug 2020 21:52:03

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 18:38:40



US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 6'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:02:49', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '5bc87b9a-abfe-4d71-b9ec-89b9a76c767e'	System	06 Aug 2020 22:01:15
User entered 'Yes (Y)'	System	06 Aug 2020 22:01:15

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:03:01', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '5bc87b9a-abfe-4d71-b9ec-89b9a76c767e'	System	06 Aug 2020 22:01:15
User entered '97.9'	System	06 Aug 2020 22:01:15

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:03:05', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '5bc87b9a-abfe-4d71-b9ec-89b9a76c767e'	System	06 Aug 2020 22:01:15
User entered 'No (N)'	System	06 Aug 2020 22:01:15

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:03:08', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '5bc87b9a-abfe-4d71-b9ec-89b9a76c767e'	System	06 Aug 2020 22:01:15
User entered '06 Aug 2020 18:03'	System	06 Aug 2020 22:01:15

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 7'	System	01 Aug 2020 18:38:40



US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:01:35', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'bcc8ef83-23b2-4fd1-8cc4-d9a951dec4e'	System	07 Aug 2020 21:59:56
User entered 'Yes (Y)'	System	07 Aug 2020 21:59:56

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:01:42', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'bcc8ef83-23b2-4fd1-8cc4-d9a951dec4e'	System	07 Aug 2020 21:59:56
User entered '98.3'	System	07 Aug 2020 21:59:56

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:01:48', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'bcc8ef83-23b2-4fd1-8cc4-d9a951decb4e'	System	07 Aug 2020 21:59:56
User entered 'No (N)'	System	07 Aug 2020 21:59:56

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:01:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'bcc8ef83-23b2-4fd1-8cc4-d9a951dec4e'	System	07 Aug 2020 21:59:56
User entered '07 Aug 2020 18:01'	System	07 Aug 2020 21:59:56

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:04:16', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34d25269-c630-4cf3-9bc6-a836a01047dd'	System	01 Aug 2020 19:02:47
User entered 'None (1)'	System	01 Aug 2020 19:02:47



US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:04:22', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34d25269-c630-4cf3-9bc6-a836a01047dd'	System	01 Aug 2020 19:02:47
User entered 'No (N)'	System	01 Aug 2020 19:02:47

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:04:27', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34d25269-c630-4cf3-9bc6-a836a01047dd'	System	01 Aug 2020 19:02:47
User entered 'No (N)'	System	01 Aug 2020 19:02:47

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:04:32', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34d25269-c630-4cf3-9bc6-a836a01047dd'	System	01 Aug 2020 19:02:47
User entered 'None (1)'	System	01 Aug 2020 19:02:47

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:04:40', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34d25269-c630-4cf3-9bc6-a836a01047dd'	System	01 Aug 2020 19:02:47
User entered '01 Aug 2020 15:04'	System	01 Aug 2020 19:02:47

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Aug 2020 14:48'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Aug 2020 17:18'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:19:55', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '8754769e-acf4-4cf9-ad75-20a9ee07792f'	System	01 Aug 2020 22:18:17
User entered 'None (1)'	System	01 Aug 2020 22:18:17



US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '8754769e-acf4-4cf9-ad75-20a9ee07792f'	System	01 Aug 2020 22:18:17
User entered 'No (N)'	System	01 Aug 2020 22:18:17

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:03', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '8754769e-acf4-4cf9-ad75-20a9ee07792f'	System	01 Aug 2020 22:18:17
User entered 'No (N)'	System	01 Aug 2020 22:18:17

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '8754769e-acf4-4cf9-ad75-20a9ee07792f'	System	01 Aug 2020 22:18:17
User entered 'None (1)'	System	01 Aug 2020 22:18:17

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:10', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '8754769e-acf4-4cf9-ad75-20a9ee07792f'	System	01 Aug 2020 22:18:17
User entered '01 Aug 2020 18:20'	System	01 Aug 2020 22:18:17

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Aug 2020 18:13'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 2'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:23', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'de757bb1-1795-40f1-8aa7-bba612f9a271'	System	02 Aug 2020 22:01:49
User entered 'None (1)'	System	02 Aug 2020 22:01:49



US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:28', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'de757bb1-1795-40f1-8aa7-bba612f9a271'	System	02 Aug 2020 22:01:49
User entered 'No (N)'	System	02 Aug 2020 22:01:49

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:31', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'de757bb1-1795-40f1-8aa7-bba612f9a271'	System	02 Aug 2020 22:01:49
User entered 'No (N)'	System	02 Aug 2020 22:01:49

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:37', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'de757bb1-1795-40f1-8aa7-bba612f9a271'	System	02 Aug 2020 22:01:49
User entered 'None (1)'	System	02 Aug 2020 22:01:49

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:41', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'de757bb1-1795-40f1-8aa7-bba612f9a271'	System	02 Aug 2020 22:01:49
User entered '02 Aug 2020 18:03'	System	02 Aug 2020 22:01:49

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 3'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:10', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'eb7756b4-bd4e-42bb-b1b7-3cb82a0b033f'	System	03 Aug 2020 22:03:47
User entered 'None (1)'	System	03 Aug 2020 22:03:47



US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:16', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'eb7756b4-bd4e-42bb-b1b7-3cb82a0b033f'	System	03 Aug 2020 22:03:47
User entered 'No (N)'	System	03 Aug 2020 22:03:47

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:20', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'eb7756b4-bd4e-42bb-b1b7-3cb82a0b033f'	System	03 Aug 2020 22:03:47
User entered 'No (N)'	System	03 Aug 2020 22:03:47

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:25', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'eb7756b4-bd4e-42bb-b1b7-3cb82a0b033f'	System	03 Aug 2020 22:03:47
User entered 'None (1)'	System	03 Aug 2020 22:03:47

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:40', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'eb7756b4-bd4e-42bb-b1b7-3cb82a0b033f' User entered '03 Aug 2020 18:05'	System	03 Aug 2020 22:03:47

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 4'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:02:38', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'cc842064-b6f3-4320-b383-13b827e5c648'	System	04 Aug 2020 22:01:10
User entered 'None (1)'	System	04 Aug 2020 22:01:10



US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:02:44', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'cc842064-b6f3-4320-b383-13b827e5c648'	System	04 Aug 2020 22:01:10
User entered 'No (N)'	System	04 Aug 2020 22:01:10

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:02:49', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'cc842064-b6f3-4320-b383-13b827e5c648'	System	04 Aug 2020 22:01:10
User entered 'No (N)'	System	04 Aug 2020 22:01:10

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:02:58', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'cc842064-b6f3-4320-b383-13b827e5c648'	System	04 Aug 2020 22:01:10
User entered 'None (1)'	System	04 Aug 2020 22:01:10

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:03:04', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'cc842064-b6f3-4320-b383-13b827e5c648'	System	04 Aug 2020 22:01:10
User entered '04 Aug 2020 18:03'	System	04 Aug 2020 22:01:10

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 5'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:01', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '41566713-709a-4c24-8989-70ca59bad5be'	System	05 Aug 2020 21:52:24
User entered 'None (1)'	System	05 Aug 2020 21:52:24



US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '41566713-709a-4c24-8989-70ca59bad5be'	System	05 Aug 2020 21:52:24
User entered 'No (N)'	System	05 Aug 2020 21:52:24

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:09', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '41566713-709a-4c24-8989-70ca59bad5be'	System	05 Aug 2020 21:52:24
User entered 'No (N)'	System	05 Aug 2020 21:52:24

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:14', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '41566713-709a-4c24-8989-70ca59bad5be'	System	05 Aug 2020 21:52:24
User entered 'None (1)'	System	05 Aug 2020 21:52:24

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:17', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '41566713-709a-4c24-8989-70ca59bad5be'	System	05 Aug 2020 21:52:24
User entered '05 Aug 2020 17:54'	System	05 Aug 2020 21:52:24

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 6'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:03:28', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a19e8d18-d24a-46b8-a63f-74c6fec9d3a5'	System	06 Aug 2020 22:01:53
User entered 'None (1)'	System	06 Aug 2020 22:01:53



US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:03:24', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a19e8d18-d24a-46b8-a63f-74c6fec9d3a5'	System	06 Aug 2020 22:01:53
User entered 'No (N)'	System	06 Aug 2020 22:01:53

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:03:35', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a19e8d18-d24a-46b8-a63f-74c6fec9d3a5'	System	06 Aug 2020 22:01:53
User entered 'No (N)'	System	06 Aug 2020 22:01:53

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:03:39', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a19e8d18-d24a-46b8-a63f-74c6fec9d3a5'	System	06 Aug 2020 22:01:53
User entered 'None (1)'	System	06 Aug 2020 22:01:53

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:03:49', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a19e8d18-d24a-46b8-a63f-74c6fec9d3a5'	System	06 Aug 2020 22:01:53
User entered '06 Aug 2020 18:03'	System	06 Aug 2020 22:01:53

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 7'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:01:58', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0989f124-3c91-4acb-b9d1-0d37db5bee96'	System	07 Aug 2020 22:00:20
User entered 'None (1)'	System	07 Aug 2020 22:00:20



US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:03', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0989f124-3c91-4acb-b9d1-0d37db5bee96'	System	07 Aug 2020 22:00:20
User entered 'No (N)'	System	07 Aug 2020 22:00:20

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0989f124-3c91-4acb-b9d1-0d37db5bee96'	System	07 Aug 2020 22:00:20
User entered 'No (N)'	System	07 Aug 2020 22:00:20

US3402153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:09', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0989f124-3c91-4acb-b9d1-0d37db5bee96'	System	07 Aug 2020 22:00:20
User entered 'None (1)'	System	07 Aug 2020 22:00:20

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:13', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0989f124-3c91-4acb-b9d1-0d37db5bee96'	System	07 Aug 2020 22:00:20
User entered '07 Aug 2020 18:02'	System	07 Aug 2020 22:00:20

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:04:46', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a152d6c5-024b-4dfa-9175-54cc08bc5752'	System	01 Aug 2020 19:03:29
User entered 'None (0)'	System	01 Aug 2020 19:03:29



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:04:48', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a152d6c5-024b-4dfa-9175-54cc08bc5752'	System	01 Aug 2020 19:03:29
User entered 'None (0)'	System	01 Aug 2020 19:03:29

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:05:04', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a152d6c5-024b-4dfa-9175-54cc08bc5752'	System	01 Aug 2020 19:03:29
User entered 'None (0)'	System	01 Aug 2020 19:03:29

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:05:08', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a152d6c5-024b-4dfa-9175-54cc08bc5752'	System	01 Aug 2020 19:03:29
User entered 'None (0)'	System	01 Aug 2020 19:03:29

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:05:11', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a152d6c5-024b-4dfa-9175-54cc08bc5752'	System	01 Aug 2020 19:03:29
User entered 'None (0)'	System	01 Aug 2020 19:03:29

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:05:13', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a152d6c5-024b-4dfa-9175-54cc08bc5752'	System	01 Aug 2020 19:03:29
User entered 'None (0)'	System	01 Aug 2020 19:03:29

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:05:19', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a152d6c5-024b-4dfa-9175-54cc08bc5752'	System	01 Aug 2020 19:03:29
User entered 'No (N)'	System	01 Aug 2020 19:03:29

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T15:05:23', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a152d6c5-024b-4dfa-9175-54cc08bc5752'	System	01 Aug 2020 19:03:29
User entered '01 Aug 2020 15:05'	System	01 Aug 2020 19:03:29

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Aug 2020 14:48'	System	01 Aug 2020 18:38:40



**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Aug 2020 17:18'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:16', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '19b876d4-0bc2-41f3-8642-94bd0122a579'	System	01 Aug 2020 22:18:53
User entered 'None (0)'	System	01 Aug 2020 22:18:53

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:20', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '19b876d4-0bc2-41f3-8642-94bd0122a579'	System	01 Aug 2020 22:18:53
User entered 'None (0)'	System	01 Aug 2020 22:18:53

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:24', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '19b876d4-0bc2-41f3-8642-94bd0122a579'	System	01 Aug 2020 22:18:53
User entered 'None (0)'	System	01 Aug 2020 22:18:53

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:26', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '19b876d4-0bc2-41f3-8642-94bd0122a579'	System	01 Aug 2020 22:18:53
User entered 'None (0)'	System	01 Aug 2020 22:18:53

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:29', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '19b876d4-0bc2-41f3-8642-94bd0122a579'	System	01 Aug 2020 22:18:53
User entered 'None (0)'	System	01 Aug 2020 22:18:53

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:31', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '19b876d4-0bc2-41f3-8642-94bd0122a579'	System	01 Aug 2020 22:18:53
User entered 'None (0)'	System	01 Aug 2020 22:18:53



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:43', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '19b876d4-0bc2-41f3-8642-94bd0122a579'	System	01 Aug 2020 22:18:53
User entered 'No (N)'	System	01 Aug 2020 22:18:53

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-01T18:20:46', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '19b876d4-0bc2-41f3-8642-94bd0122a579'	System	01 Aug 2020 22:18:53
User entered '01 Aug 2020 18:20'	System	01 Aug 2020 22:18:53

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Aug 2020 18:13'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 2'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:47', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1485fb38-dccc-47dd-a6e3-cd90f65f369a'	System	02 Aug 2020 22:02:23
User entered 'None (0)'	System	02 Aug 2020 22:02:23

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:50', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1485fb38-dccc-47dd-a6e3-cd90f65f369a'	System	02 Aug 2020 22:02:23
User entered 'None (0)'	System	02 Aug 2020 22:02:23

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:54', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1485fb38-dccc-47dd-a6e3-cd90f65f369a'	System	02 Aug 2020 22:02:23
User entered 'None (0)'	System	02 Aug 2020 22:02:23



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:03:57', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1485fb38-dccc-47dd-a6e3-cd90f65f369a'	System	02 Aug 2020 22:02:23
User entered 'None (0)'	System	02 Aug 2020 22:02:23

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1485fb38-dccc-47dd-a6e3-cd90f65f369a'	System	02 Aug 2020 22:02:23
User entered 'None (0)'	System	02 Aug 2020 22:02:23

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:04:04', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1485fb38-dccc-47dd-a6e3-cd90f65f369a'	System	02 Aug 2020 22:02:23
User entered 'None (0)'	System	02 Aug 2020 22:02:23

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:04:12', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1485fb38-dccc-47dd-a6e3-cd90f65f369a'	System	02 Aug 2020 22:02:23
User entered 'No (N)'	System	02 Aug 2020 22:02:23

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-02T18:04:16', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1485fb38-dccc-47dd-a6e3-cd90f65f369a'	System	02 Aug 2020 22:02:23
User entered '02 Aug 2020 18:04'	System	02 Aug 2020 22:02:23

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 3'	System	01 Aug 2020 18:38:40



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:46', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34abfec9-e6bb-43b3-bada-eca7e15697fb'	System	03 Aug 2020 22:04:25
User entered 'None (0)'	System	03 Aug 2020 22:04:25

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:49', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34abfec9-e6bb-43b3-bada-eca7e15697fb'	System	03 Aug 2020 22:04:25
User entered 'None (0)'	System	03 Aug 2020 22:04:25

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34abfec9-e6bb-43b3-bada-eca7e15697fb'	System	03 Aug 2020 22:04:25
User entered 'None (0)'	System	03 Aug 2020 22:04:25

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:55', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34abfec9-e6bb-43b3-bada-eca7e15697fb'	System	03 Aug 2020 22:04:25
User entered 'None (0)'	System	03 Aug 2020 22:04:25

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:05:58', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34abfec9-e6bb-43b3-bada-eca7e15697fb'	System	03 Aug 2020 22:04:25
User entered 'None (0)'	System	03 Aug 2020 22:04:25

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:06:01', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34abfec9-e6bb-43b3-bada-eca7e15697fb'	System	03 Aug 2020 22:04:25
User entered 'None (0)'	System	03 Aug 2020 22:04:25

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:06:08', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34abfec9-e6bb-43b3-bada-eca7e15697fb'	System	03 Aug 2020 22:04:25
User entered 'No (N)'	System	03 Aug 2020 22:04:25

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-03T18:06:16', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34abfec9-e6bb-43b3-bada-eca7e15697fb'	System	03 Aug 2020 22:04:25
User entered '03 Aug 2020 18:06'	System	03 Aug 2020 22:04:25



**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 4'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:03:20', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6bcba99-a917-40c3-b216-b890ef781ba6'	System	04 Aug 2020 22:02:02
User entered 'None (0)'	System	04 Aug 2020 22:02:02

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:03:25', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6bcba99-a917-40c3-b216-b890ef781ba6'	System	04 Aug 2020 22:02:02
User entered 'None (0)'	System	04 Aug 2020 22:02:02

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:03:28', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6bcba99-a917-40c3-b216-b890ef781ba6'	System	04 Aug 2020 22:02:02
User entered 'None (0)'	System	04 Aug 2020 22:02:02

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:03:35', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6bcba99-a917-40c3-b216-b890ef781ba6'	System	04 Aug 2020 22:02:02
User entered 'None (0)'	System	04 Aug 2020 22:02:02

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:03:39', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6bcba99-a917-40c3-b216-b890ef781ba6'	System	04 Aug 2020 22:02:02
User entered 'None (0)'	System	04 Aug 2020 22:02:02



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:03:43', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6bcba99-a917-40c3-b216-b890ef781ba6'	System	04 Aug 2020 22:02:02
User entered 'None (0)'	System	04 Aug 2020 22:02:02

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:03:51', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6bcba99-a917-40c3-b216-b890ef781ba6'	System	04 Aug 2020 22:02:02
User entered 'No (N)'	System	04 Aug 2020 22:02:02

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-04T18:03:54', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6bcba99-a917-40c3-b216-b890ef781ba6'	System	04 Aug 2020 22:02:02
User entered '04 Aug 2020 18:03'	System	04 Aug 2020 22:02:02

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 5'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:22', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e865711a-28cb-4ce4-8ad5-f1f379f88b35'	System	05 Aug 2020 21:52:58
User entered 'None (0)'	System	05 Aug 2020 21:52:58

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:25', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e865711a-28cb-4ce4-8ad5-f1f379f88b35'	System	05 Aug 2020 21:52:58
User entered 'None (0)'	System	05 Aug 2020 21:52:58



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:27', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e865711a-28cb-4ce4-8ad5-f1f379f88b35'	System	05 Aug 2020 21:52:58
User entered 'None (0)'	System	05 Aug 2020 21:52:58

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:31', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e865711a-28cb-4ce4-8ad5-f1f379f88b35'	System	05 Aug 2020 21:52:58
User entered 'None (0)'	System	05 Aug 2020 21:52:58

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:33', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e865711a-28cb-4ce4-8ad5-f1f379f88b35'	System	05 Aug 2020 21:52:58
User entered 'None (0)'	System	05 Aug 2020 21:52:58

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:38', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e865711a-28cb-4ce4-8ad5-f1f379f88b35'	System	05 Aug 2020 21:52:58
User entered 'None (0)'	System	05 Aug 2020 21:52:58

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:42', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e865711a-28cb-4ce4-8ad5-f1f379f88b35'	System	05 Aug 2020 21:52:58
User entered 'No (N)'	System	05 Aug 2020 21:52:58

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-05T17:54:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e865711a-28cb-4ce4-8ad5-f1f379f88b35'	System	05 Aug 2020 21:52:58
User entered '05 Aug 2020 17:54'	System	05 Aug 2020 21:52:58

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 18:38:40



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 6'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:03:58', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eefc65d-6f39-4019-bafd-20e967d99c23'	System	06 Aug 2020 22:02:24
User entered 'None (0)'	System	06 Aug 2020 22:02:24

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eefc65d-6f39-4019-bafd-20e967d99c23'	System	06 Aug 2020 22:02:24
User entered 'None (0)'	System	06 Aug 2020 22:02:24

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:04:03', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eefc65d-6f39-4019-bafd-20e967d99c23'	System	06 Aug 2020 22:02:24
User entered 'None (0)'	System	06 Aug 2020 22:02:24

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:04:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eefc65d-6f39-4019-bafd-20e967d99c23'	System	06 Aug 2020 22:02:24
User entered 'None (0)'	System	06 Aug 2020 22:02:24

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:04:09', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eefc65d-6f39-4019-bafd-20e967d99c23'	System	06 Aug 2020 22:02:24
User entered 'None (0)'	System	06 Aug 2020 22:02:24

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:04:13', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eefc65d-6f39-4019-bafd-20e967d99c23'	System	06 Aug 2020 22:02:24
User entered 'None (0)'	System	06 Aug 2020 22:02:24

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:04:17', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eefc65d-6f39-4019-bafd-20e967d99c23'	System	06 Aug 2020 22:02:24
User entered 'No (N)'	System	06 Aug 2020 22:02:24



**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-06T18:04:20', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eefc65d-6f39-4019-bafd-20e967d99c23'	System	06 Aug 2020 22:02:24
User entered '06 Aug 2020 18:04'	System	06 Aug 2020 22:02:24

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 7'	System	01 Aug 2020 18:38:40

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:19', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff7e112-9a2e-4220-856d-8a8fee6f9cca'	System	07 Aug 2020 22:00:50
User entered 'None (0)'	System	07 Aug 2020 22:00:50

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:21', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff7e112-9a2e-4220-856d-8a8fee6f9cca'	System	07 Aug 2020 22:00:50
User entered 'None (0)'	System	07 Aug 2020 22:00:50

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:26', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff7e112-9a2e-4220-856d-8a8fee6f9cca'	System	07 Aug 2020 22:00:50
User entered 'None (0)'	System	07 Aug 2020 22:00:50

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:30', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff7e112-9a2e-4220-856d-8a8fee6f9cca'	System	07 Aug 2020 22:00:50
User entered 'None (0)'	System	07 Aug 2020 22:00:50



US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:33', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff7e112-9a2e-4220-856d-8a8fee6f9cca'	System	07 Aug 2020 22:00:50
User entered 'None (0)'	System	07 Aug 2020 22:00:50

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:36', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff7e112-9a2e-4220-856d-8a8fee6f9cca'	System	07 Aug 2020 22:00:50
User entered 'None (0)'	System	07 Aug 2020 22:00:50

US3402153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:41', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff7e112-9a2e-4220-856d-8a8fee6f9cca'	System	07 Aug 2020 22:00:50
User entered 'No (N)'	System	07 Aug 2020 22:00:50

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-08-07T18:02:44', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff7e112-9a2e-4220-856d-8a8fee6f9cca'	System	07 Aug 2020 22:00:50
User entered '07 Aug 2020 18:02'	System	07 Aug 2020 22:00:50

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 18:38:40

US3402153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	24 Aug 2020 17:58:49
User entered 'Yes (Y)'	System	24 Aug 2020 17:56:52
	Traci Hull (b) (4)	24 Aug 2020 17:56:52
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '8 Aug 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	24 Aug 2020 17:58:49
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 17:56:52



**US3402153**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	24 Aug 2020 17:56:52

**US3402153**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 17:56:52

**US3402153**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 17:58:56

**US3402153**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'I'	System	24 Aug 2020 17:58:56

**US3402153**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	24 Aug 2020 17:59:17

**US3402153**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '16 Aug 2020'	Traci Hull (b) (4)	24 Aug 2020 17:59:17

**US3402153**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	24 Aug 2020 17:59:17

**US3402153**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 17:59:17



**US3402153**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 17:59:25

**US3402153**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'I'	System	24 Aug 2020 17:59:25

**US3402153**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 17:59:40

**US3402153**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '22 Aug 2020'	Traci Hull (b) (4)	24 Aug 2020 17:59:40

**US3402153**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	24 Aug 2020 17:59:40

**US3402153**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 17:59:40

**US3402153**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 17:59:47

**US3402153**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'I'	System	24 Aug 2020 17:59:47



US3402153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	01 Sep 2020 21:20:08

US3402153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 21:20:08

US3402153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	01 Sep 2020 21:20:08

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'VISIT2'	System	01 Sep 2020 21:20:08

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 21:21:26

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '15:52'	Traci Hull (b) (4)	01 Sep 2020 21:21:26



**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered '1 Sep 2020 15:52'	System	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '37.3' C	Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:21:26

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '99'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'bpm'	System	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '15'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'breaths/min'	System	01 Sep 2020 21:21:26



US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '122'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'mmHg'	System	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '82'	Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'mmHg'	System	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:21:26

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '17:10'	Traci Hull (b) (4)	01 Sep 2020 21:21:26



**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered '1 Sep 2020 17:10'	System	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '36.9' C	Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:21:26

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '95'	Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'bpm'	System	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '15'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'breaths/min'	System	01 Sep 2020 21:21:26



US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '124'	Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'mmHg'	System	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '82'	Traci Hull (b) (4)	01 Sep 2020 21:21:26

US3402153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'mmHg'	System	01 Sep 2020 21:21:26

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	01 Sep 2020 21:21:33
	(b) (4)	

US3402153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:21:33

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 20:53:27

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 20:53:27



US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Abigail Wine (b) (4)	01 Sep 2020 20:53:27

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 20:53:27

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Sep 2020'	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 20:53:27

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '16:38'	(b) (4) Abigail Wine (b) (4)	01 Sep 2020 20:53:27

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered '1 Sep 2020 16:38'	System	01 Sep 2020 20:53:27

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Left Arm (LEFT ARM)'	Abigail Wine (b) (4)	01 Sep 2020 20:53:27

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'ONCE'	System	01 Sep 2020 20:53:27

US3402153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 20:53:27



US3402153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 21:22:01

US3402153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Sep 2020'	Traci Hull (b) (4)	01 Sep 2020 21:22:01

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '16:11'	Traci Hull (b) (4)	01 Sep 2020 21:22:01

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered '1 Sep 2020 16:11'	System	01 Sep 2020 21:22:01

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:42:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '1 Sep 2020'	Traci Hull (b) (4)	01 Sep 2020 21:22:13

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:22:13

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:22:13

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:42:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '16:14'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:22:13



**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered '1 Sep 2020 16:14'	System	01 Sep 2020 21:22:13

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:22:13

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 21:22:13

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:42:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Traci Hull (b) (4)	01 Sep 2020 21:22:13

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered empty.	System	01 Sep 2020 21:22:13

US3402153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 21:22:17

**US3402153**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered '1'	System	01 Sep 2020 21:22:17

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:15:49', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'acd41737-5c49-4399-9028-dcc6ceb507c1'	System	01 Sep 2020 21:14:08
User entered 'Yes (Y)'	System	01 Sep 2020 21:14:08

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:16:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'acd41737-5c49-4399-9028-dcc6ceb507c1' User entered '98.4'	System	01 Sep 2020 21:14:08
	System	01 Sep 2020 21:14:08

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:16:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'acd41737-5c49-4399-9028-dcc6ceb507c1'	System	01 Sep 2020 21:14:08
User entered 'No (N)'	System	01 Sep 2020 21:14:08

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:16:14', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'acd41737-5c49-4399-9028-dcc6ceb507c1'	System	01 Sep 2020 21:14:08
User entered '01 Sep 2020 17:16'	System	01 Sep 2020 21:14:08

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Sep 2020 16:58'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Sep 2020 19:28'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:04:28', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'fff75721-b786-410b-86d0-628d73c3f6c2'	System	02 Sep 2020 01:02:41
User entered 'Yes (Y)'	System	02 Sep 2020 01:02:41



US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:04:37', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'fff75721-b786-410b-86d0-628d73c3f6c2'	System	02 Sep 2020 01:02:41
User entered '98.3'	System	02 Sep 2020 01:02:41

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:04:44', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'fff75721-b786-410b-86d0-628d73c3f6c2'	System	02 Sep 2020 01:02:41
User entered 'No (N)'	System	02 Sep 2020 01:02:41

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:04:47', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'fff75721-b786-410b-86d0-628d73c3f6c2'	System	02 Sep 2020 01:02:41
User entered '01 Sep 2020 21:04'	System	02 Sep 2020 01:02:41

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Sep 2020 20:23'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 2'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:18:39', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1f2e0149-6240-4424-b6b4-5459370d30c3'	System	02 Sep 2020 22:16:43
User entered 'Yes (Y)'	System	02 Sep 2020 22:16:43

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:18:44', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1f2e0149-6240-4424-b6b4-5459370d30c3'	System	02 Sep 2020 22:16:43
User entered '98.1'	System	02 Sep 2020 22:16:43



US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:18:49', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1f2e0149-6240-4424-b6b4-5459370d30c3'	System	02 Sep 2020 22:16:43
User entered 'No (N)'	System	02 Sep 2020 22:16:43

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:18:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1f2e0149-6240-4424-b6b4-5459370d30c3'	System	02 Sep 2020 22:16:43
User entered '02 Sep 2020 18:18'	System	02 Sep 2020 22:16:43

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 3'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:31:40', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c7046e35-9502-42d3-bcba-7a965feddc6d'	System	03 Sep 2020 21:29:44
User entered 'Yes (Y)'	System	03 Sep 2020 21:29:44

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:31:44', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c7046e35-9502-42d3-bcba-7a965feddc6d'	System	03 Sep 2020 21:29:44
User entered '98.2'	System	03 Sep 2020 21:29:44

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:31:50', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c7046e35-9502-42d3-bcba-7a965feddc6d'	System	03 Sep 2020 21:29:44
User entered 'No (N)'	System	03 Sep 2020 21:29:44



US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:31:53', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c7046e35-9502-42d3-bcba-7a965feddc6d'	System	03 Sep 2020 21:29:44
User entered '03 Sep 2020 17:31'	System	03 Sep 2020 21:29:44

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 4'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:02', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0c32aa51-5762-4392-b9b1-833f87621f0d'	System	04 Sep 2020 22:34:07
User entered 'Yes (Y)'	System	04 Sep 2020 22:34:07

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0c32aa51-5762-4392-b9b1-833f87621f0d'	System	04 Sep 2020 22:34:07
User entered '98.3'	System	04 Sep 2020 22:34:07

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:13', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0c32aa51-5762-4392-b9b1-833f87621f0d'	System	04 Sep 2020 22:34:07
User entered 'No (N)'	System	04 Sep 2020 22:34:07

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:15', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0c32aa51-5762-4392-b9b1-833f87621f0d'	System	04 Sep 2020 22:34:07
User entered '04 Sep 2020 18:36'	System	04 Sep 2020 22:34:07



**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 5'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:08', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db14c175-fbc9-42d2-9bc2-54fdc9fe4d07'	System	05 Sep 2020 21:30:08
User entered 'Yes (Y)'	System	05 Sep 2020 21:30:08

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:12', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db14c175-fbc9-42d2-9bc2-54fdc9fe4d07'	System	05 Sep 2020 21:30:08
User entered '98.5'	System	05 Sep 2020 21:30:08

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:15', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db14c175-fbc9-42d2-9bc2-54fdc9fe4d07'	System	05 Sep 2020 21:30:08
User entered 'No (N)'	System	05 Sep 2020 21:30:08

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:18', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db14c175-fbc9-42d2-9bc2-54fdc9fe4d07'	System	05 Sep 2020 21:30:08
User entered '05 Sep 2020 17:32'	System	05 Sep 2020 21:30:08

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:53:27



**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 6'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:00:48', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '67aa01bd-9937-454b-a41a-b8b74a98a8b3'	System	06 Sep 2020 21:58:56
User entered 'Yes (Y)'	System	06 Sep 2020 21:58:56

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:00:53', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '67aa01bd-9937-454b-a41a-b8b74a98a8b3' User entered '97.9'	System	06 Sep 2020 21:58:56
	System	06 Sep 2020 21:58:56

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:00:59', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '67aa01bd-9937-454b-a41a-b8b74a98a8b3'	System	06 Sep 2020 21:58:56
User entered 'No (N)'	System	06 Sep 2020 21:58:56

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '67aa01bd-9937-454b-a41a-b8b74a98a8b3'	System	06 Sep 2020 21:58:56
User entered '06 Sep 2020 18:01'	System	06 Sep 2020 21:58:56

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:42:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 7'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:17', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '15f07d83-5849-41d1-974e-2f967803b6a5'	System	07 Sep 2020 23:12:16
User entered 'Yes (Y)'	System	07 Sep 2020 23:12:16

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:21', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '15f07d83-5849-41d1-974e-2f967803b6a5' User entered '98.1'	System	07 Sep 2020 23:12:16

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:25', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '15f07d83-5849-41d1-974e-2f967803b6a5'	System	07 Sep 2020 23:12:16
User entered 'No (N)'	System	07 Sep 2020 23:12:16

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:28', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '15f07d83-5849-41d1-974e-2f967803b6a5'	System	07 Sep 2020 23:12:16
User entered '07 Sep 2020 19:14'	System	07 Sep 2020 23:12:16

US3402153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:42:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:16:23', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '6f090332-bf2b-42b5-926a-789552022f30'	System	01 Sep 2020 21:14:55
User entered 'None (1)'	System	01 Sep 2020 21:14:55

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:16:41', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '6f090332-bf2b-42b5-926a-789552022f30'	System	01 Sep 2020 21:14:55
User entered 'No (N)'	System	01 Sep 2020 21:14:55

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:16:46', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '6f090332-bf2b-42b5-926a-789552022f30'	System	01 Sep 2020 21:14:55
User entered 'No (N)'	System	01 Sep 2020 21:14:55

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:16:57', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '6f090332-bf2b-42b5-926a-789552022f30'	System	01 Sep 2020 21:14:55
User entered 'None (1)'	System	01 Sep 2020 21:14:55

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:17:01', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '6f090332-bf2b-42b5-926a-789552022f30'	System	01 Sep 2020 21:14:55
User entered '01 Sep 2020 17:17'	System	01 Sep 2020 21:14:55

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Sep 2020 16:58'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Sep 2020 19:28'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:04:56', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '5865a39a-fdd4-4158-a67d-b06e757f90c3'	System	02 Sep 2020 01:03:08
User entered 'None (1)'	System	02 Sep 2020 01:03:08

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '5865a39a-fdd4-4158-a67d-b06e757f90c3'	System	02 Sep 2020 01:03:08
User entered 'No (N)'	System	02 Sep 2020 01:03:08

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:03', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '5865a39a-fdd4-4158-a67d-b06e757f90c3'	System	02 Sep 2020 01:03:08
User entered 'No (N)'	System	02 Sep 2020 01:03:08

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:09', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '5865a39a-fdd4-4158-a67d-b06e757f90c3'	System	02 Sep 2020 01:03:08
User entered 'None (1)'	System	02 Sep 2020 01:03:08

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:16', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '5865a39a-fdd4-4158-a67d-b06e757f90c3'	System	02 Sep 2020 01:03:08
User entered '01 Sep 2020 21:05'	System	02 Sep 2020 01:03:08

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Sep 2020 20:23'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 2'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:18:57', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9402925c-9b0e-491d-91f1-eb087f6dcf7c'	System	02 Sep 2020 22:17:00
User entered 'None (1)'	System	02 Sep 2020 22:17:00

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9402925c-9b0e-491d-91f1-eb087f6dcf7c'	System	02 Sep 2020 22:17:00
User entered 'No (N)'	System	02 Sep 2020 22:17:00

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:03', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9402925c-9b0e-491d-91f1-eb087f6dcf7c'	System	02 Sep 2020 22:17:00
User entered 'No (N)'	System	02 Sep 2020 22:17:00

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:07', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9402925c-9b0e-491d-91f1-eb087f6dcf7c'	System	02 Sep 2020 22:17:00
User entered 'None (1)'	System	02 Sep 2020 22:17:00

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:10', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9402925c-9b0e-491d-91f1-eb087f6dcf7c'	System	02 Sep 2020 22:17:00
User entered '02 Sep 2020 18:19'	System	02 Sep 2020 22:17:00

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 3'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:31:59', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6e9b709-fb9c-4d52-b500-d74707659960'	System	03 Sep 2020 21:30:04
User entered 'None (1)'	System	03 Sep 2020 21:30:04

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:02', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6e9b709-fb9c-4d52-b500-d74707659960'	System	03 Sep 2020 21:30:04
User entered 'No (N)'	System	03 Sep 2020 21:30:04

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:05', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6e9b709-fb9c-4d52-b500-d74707659960'	System	03 Sep 2020 21:30:04
User entered 'No (N)'	System	03 Sep 2020 21:30:04

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:10', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6e9b709-fb9c-4d52-b500-d74707659960'	System	03 Sep 2020 21:30:04
User entered 'None (1)'	System	03 Sep 2020 21:30:04

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:12', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a6e9b709-fb9c-4d52-b500-d74707659960'	System	03 Sep 2020 21:30:04
User entered '03 Sep 2020 17:32'	System	03 Sep 2020 21:30:04

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 4'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:21', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a2d77aa6-6379-45b4-8a9f-29cd3e226ccc'	System	04 Sep 2020 22:34:38
User entered 'None (1)'	System	04 Sep 2020 22:34:38

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:26', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a2d77aa6-6379-45b4-8a9f-29cd3e226ccc'	System	04 Sep 2020 22:34:38
User entered 'No (N)'	System	04 Sep 2020 22:34:38

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:31', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a2d77aa6-6379-45b4-8a9f-29cd3e226ccc'	System	04 Sep 2020 22:34:38
User entered 'No (N)'	System	04 Sep 2020 22:34:38

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:36', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a2d77aa6-6379-45b4-8a9f-29cd3e226ccc'	System	04 Sep 2020 22:34:38
User entered 'None (1)'	System	04 Sep 2020 22:34:38

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:46', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a2d77aa6-6379-45b4-8a9f-29cd3e226ccc'	System	04 Sep 2020 22:34:38
User entered '04 Sep 2020 18:36'	System	04 Sep 2020 22:34:38

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 5'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:25', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '738a7242-c02e-437f-bdf2-49348b1a49e7'	System	05 Sep 2020 21:30:28
User entered 'None (1)'	System	05 Sep 2020 21:30:28

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:28', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '738a7242-c02e-437f-bdf2-49348b1a49e7'	System	05 Sep 2020 21:30:28
User entered 'No (N)'	System	05 Sep 2020 21:30:28

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:32', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '738a7242-c02e-437f-bdf2-49348b1a49e7'	System	05 Sep 2020 21:30:28
User entered 'No (N)'	System	05 Sep 2020 21:30:28

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:34', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '738a7242-c02e-437f-bdf2-49348b1a49e7'	System	05 Sep 2020 21:30:28
User entered 'None (1)'	System	05 Sep 2020 21:30:28

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:38', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '738a7242-c02e-437f-bdf2-49348b1a49e7'	System	05 Sep 2020 21:30:28
User entered '05 Sep 2020 17:32'	System	05 Sep 2020 21:30:28

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 6'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:13', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '4bd8bb20-6914-4d66-8259-7cb43f13e994'	System	06 Sep 2020 21:59:18
User entered 'None (1)'	System	06 Sep 2020 21:59:18

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:19', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '4bd8bb20-6914-4d66-8259-7cb43f13e994'	System	06 Sep 2020 21:59:18
User entered 'No (N)'	System	06 Sep 2020 21:59:18

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:22', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '4bd8bb20-6914-4d66-8259-7cb43f13e994'	System	06 Sep 2020 21:59:18
User entered 'No (N)'	System	06 Sep 2020 21:59:18

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:26', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '4bd8bb20-6914-4d66-8259-7cb43f13e994'	System	06 Sep 2020 21:59:18
User entered 'None (1)'	System	06 Sep 2020 21:59:18

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:29', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '4bd8bb20-6914-4d66-8259-7cb43f13e994'	System	06 Sep 2020 21:59:18
User entered '06 Sep 2020 18:01'	System	06 Sep 2020 21:59:18

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 7'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:33', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a939842a-752b-4c35-8734-bc703e413a87'	System	07 Sep 2020 23:12:36
User entered 'None (1)'	System	07 Sep 2020 23:12:36

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:37', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a939842a-752b-4c35-8734-bc703e413a87'	System	07 Sep 2020 23:12:36
User entered 'No (N)'	System	07 Sep 2020 23:12:36

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:40', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a939842a-752b-4c35-8734-bc703e413a87'	System	07 Sep 2020 23:12:36
User entered 'No (N)'	System	07 Sep 2020 23:12:36

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:43', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a939842a-752b-4c35-8734-bc703e413a87'	System	07 Sep 2020 23:12:36
User entered 'None (1)'	System	07 Sep 2020 23:12:36

US3402153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:42:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:46', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a939842a-752b-4c35-8734-bc703e413a87'	System	07 Sep 2020 23:12:36
User entered '07 Sep 2020 19:14'	System	07 Sep 2020 23:12:36

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:17:07', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3da0341a-bc40-4cf9-8fa6-407ea5f4d6df' User entered 'None (0)'	System	01 Sep 2020 21:15:26
	System	01 Sep 2020 21:15:26

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:17:09', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3da0341a-bc40-4cf9-8fa6-407ea5f4d6df' User entered 'None (0)'	System	01 Sep 2020 21:15:26
	System	01 Sep 2020 21:15:26

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:17:12', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3da0341a-bc40-4cf9-8fa6-407ea5f4d6df' User entered 'None (0)'	System	01 Sep 2020 21:15:26
	System	01 Sep 2020 21:15:26

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:17:17', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3da0341a-bc40-4cf9-8fa6-407ea5f4d6df' User entered 'None (0)'	System	01 Sep 2020 21:15:26
	System	01 Sep 2020 21:15:26

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:17:20', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3da0341a-bc40-4cf9-8fa6-407ea5f4d6df' User entered 'None (0)'	System	01 Sep 2020 21:15:26
	System	01 Sep 2020 21:15:26

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:17:23', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3da0341a-bc40-4cf9-8fa6-407ea5f4d6df' User entered 'None (0)'	System	01 Sep 2020 21:15:26
	System	01 Sep 2020 21:15:26

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:17:28', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3da0341a-bc40-4cf9-8fa6-407ea5f4d6df'	System	01 Sep 2020 21:15:26
User entered 'No (N)'	System	01 Sep 2020 21:15:26

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T17:17:32', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3da0341a-bc40-4cf9-8fa6-407ea5f4d6df'	System	01 Sep 2020 21:15:26
User entered '01 Sep 2020 17:17'	System	01 Sep 2020 21:15:26



**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Sep 2020 16:58'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Sep 2020 19:28'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:21', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34f67c0c-10cd-4173-b47f-f5ec0df128a8'	System	02 Sep 2020 01:03:42
User entered 'None (0)'	System	02 Sep 2020 01:03:42

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:24', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34f67c0c-10cd-4173-b47f-f5ec0df128a8'	System	02 Sep 2020 01:03:42
User entered 'None (0)'	System	02 Sep 2020 01:03:42

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:28', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34f67c0c-10cd-4173-b47f-f5ec0df128a8'	System	02 Sep 2020 01:03:42
User entered 'None (0)'	System	02 Sep 2020 01:03:42

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:32', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34f67c0c-10cd-4173-b47f-f5ec0df128a8'	System	02 Sep 2020 01:03:42
User entered 'None (0)'	System	02 Sep 2020 01:03:42

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:35', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34f67c0c-10cd-4173-b47f-f5ec0df128a8'	System	02 Sep 2020 01:03:42
User entered 'None (0)'	System	02 Sep 2020 01:03:42



US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:40', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34f67c0c-10cd-4173-b47f-f5ec0df128a8'	System	02 Sep 2020 01:03:42
User entered 'None (0)'	System	02 Sep 2020 01:03:42

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:46', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34f67c0c-10cd-4173-b47f-f5ec0df128a8'	System	02 Sep 2020 01:03:42
User entered 'No (N)'	System	02 Sep 2020 01:03:42

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-01T21:05:50', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '34f67c0c-10cd-4173-b47f-f5ec0df128a8'	System	02 Sep 2020 01:03:42
User entered '01 Sep 2020 21:05'	System	02 Sep 2020 01:03:42

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '01 Sep 2020 20:23'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 2'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:14', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '078384aa-82a8-4071-826a-2cfffefc112a'	System	02 Sep 2020 22:17:24
User entered 'None (0)'	System	02 Sep 2020 22:17:24

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:16', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '078384aa-82a8-4071-826a-2cfffefc112a'	System	02 Sep 2020 22:17:24
User entered 'None (0)'	System	02 Sep 2020 22:17:24



US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:18', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '078384aa-82a8-4071-826a-2cfffefc112a'	System	02 Sep 2020 22:17:24
User entered 'None (0)'	System	02 Sep 2020 22:17:24

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:21', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '078384aa-82a8-4071-826a-2cfffefc112a'	System	02 Sep 2020 22:17:24
User entered 'None (0)'	System	02 Sep 2020 22:17:24

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:23', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '078384aa-82a8-4071-826a-2cffffcfc112a'	System	02 Sep 2020 22:17:24
User entered 'None (0)'	System	02 Sep 2020 22:17:24

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:25', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '078384aa-82a8-4071-826a-2cfffefc112a'	System	02 Sep 2020 22:17:24
User entered 'None (0)'	System	02 Sep 2020 22:17:24

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:31', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '078384aa-82a8-4071-826a-2cffffcfc112a'	System	02 Sep 2020 22:17:24
User entered 'No (N)'	System	02 Sep 2020 22:17:24

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-02T18:19:34', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '078384aa-82a8-4071-826a-2cfffefc112a'	System	02 Sep 2020 22:17:24
User entered '02 Sep 2020 18:19'	System	02 Sep 2020 22:17:24

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 20:53:27



US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 3'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:17', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f358fa14-7644-4093-9bf4-930748d7934b'	System	03 Sep 2020 21:30:31
User entered 'None (0)'	System	03 Sep 2020 21:30:31

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:19', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f358fa14-7644-4093-9bf4-930748d7934b'	System	03 Sep 2020 21:30:31
User entered 'None (0)'	System	03 Sep 2020 21:30:31

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:21', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f358fa14-7644-4093-9bf4-930748d7934b'	System	03 Sep 2020 21:30:31
User entered 'None (0)'	System	03 Sep 2020 21:30:31

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:24', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f358fa14-7644-4093-9bf4-930748d7934b' User entered 'None (0)'	System	03 Sep 2020 21:30:31
	System	03 Sep 2020 21:30:31

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:27', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f358fa14-7644-4093-9bf4-930748d7934b' User entered 'None (0)'	System	03 Sep 2020 21:30:31
	System	03 Sep 2020 21:30:31

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:29', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f358fa14-7644-4093-9bf4-930748d7934b'	System	03 Sep 2020 21:30:31
User entered 'None (0)'	System	03 Sep 2020 21:30:31

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:35', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f358fa14-7644-4093-9bf4-930748d7934b'	System	03 Sep 2020 21:30:31
User entered 'No (N)'	System	03 Sep 2020 21:30:31



**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-03T17:32:38', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f358fa14-7644-4093-9bf4-930748d7934b'	System	03 Sep 2020 21:30:31
User entered '03 Sep 2020 17:32'	System	03 Sep 2020 21:30:31

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 4'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:53', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ddfde279-0ed5-4ab0-8d92-0b765d8b2e18'	System	04 Sep 2020 22:35:17
User entered 'None (0)'	System	04 Sep 2020 22:35:17

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:36:57', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ddfde279-0ed5-4ab0-8d92-0b765d8b2e18'	System	04 Sep 2020 22:35:17
User entered 'None (0)'	System	04 Sep 2020 22:35:17

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:37:01', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ddfde279-0ed5-4ab0-8d92-0b765d8b2e18'	System	04 Sep 2020 22:35:17
User entered 'None (0)'	System	04 Sep 2020 22:35:17

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:37:04', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ddfde279-0ed5-4ab0-8d92-0b765d8b2e18'	System	04 Sep 2020 22:35:17
User entered 'None (0)'	System	04 Sep 2020 22:35:17



US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:37:11', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ddfde279-0ed5-4ab0-8d92-0b765d8b2e18'	System	04 Sep 2020 22:35:17
User entered 'None (0)'	System	04 Sep 2020 22:35:17

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:37:16', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ddfde279-0ed5-4ab0-8d92-0b765d8b2e18'	System	04 Sep 2020 22:35:17
User entered 'None (0)'	System	04 Sep 2020 22:35:17

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:37:21', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ddfde279-0ed5-4ab0-8d92-0b765d8b2e18'	System	04 Sep 2020 22:35:17
User entered 'No (N)'	System	04 Sep 2020 22:35:17

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-04T18:37:24', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ddfde279-0ed5-4ab0-8d92-0b765d8b2e18'	System	04 Sep 2020 22:35:17
User entered '04 Sep 2020 18:37'	System	04 Sep 2020 22:35:17

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 5'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:43', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c8345ec6-fba5-44f2-a740-5daeb1e26687'	System	05 Sep 2020 21:30:55
User entered 'None (0)'	System	05 Sep 2020 21:30:55



US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:45', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c8345ec6-fba5-44f2-a740-5daeb1e26687'	System	05 Sep 2020 21:30:55
User entered 'None (0)'	System	05 Sep 2020 21:30:55

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:48', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c8345ec6-fba5-44f2-a740-5daeb1e26687'	System	05 Sep 2020 21:30:55
User entered 'None (0)'	System	05 Sep 2020 21:30:55

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:51', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c8345ec6-fba5-44f2-a740-5daeb1e26687'	System	05 Sep 2020 21:30:55
User entered 'None (0)'	System	05 Sep 2020 21:30:55

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:53', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c8345ec6-fba5-44f2-a740-5daeb1e26687'	System	05 Sep 2020 21:30:55
User entered 'None (0)'	System	05 Sep 2020 21:30:55

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:32:56', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c8345ec6-fba5-44f2-a740-5daeb1e26687'	System	05 Sep 2020 21:30:55
User entered 'None (0)'	System	05 Sep 2020 21:30:55

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:33:02', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c8345ec6-fba5-44f2-a740-5daeb1e26687'	System	05 Sep 2020 21:30:55
User entered 'No (N)'	System	05 Sep 2020 21:30:55

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-05T17:33:05', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c8345ec6-fba5-44f2-a740-5daeb1e26687'	System	05 Sep 2020 21:30:55
User entered '05 Sep 2020 17:33'	System	05 Sep 2020 21:30:55

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 20:53:27



**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 6'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:36', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff54906-8803-4b9d-901d-0b04c394070f'	System	06 Sep 2020 21:59:45
User entered 'None (0)'	System	06 Sep 2020 21:59:45

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:39', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff54906-8803-4b9d-901d-0b04c394070f'	System	06 Sep 2020 21:59:45
User entered 'None (0)'	System	06 Sep 2020 21:59:45

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:42', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff54906-8803-4b9d-901d-0b04c394070f'	System	06 Sep 2020 21:59:45
User entered 'None (0)'	System	06 Sep 2020 21:59:45

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:44', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff54906-8803-4b9d-901d-0b04c394070f'	System	06 Sep 2020 21:59:45
User entered 'None (0)'	System	06 Sep 2020 21:59:45

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:47', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff54906-8803-4b9d-901d-0b04c394070f'	System	06 Sep 2020 21:59:45
User entered 'None (0)'	System	06 Sep 2020 21:59:45

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:49', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff54906-8803-4b9d-901d-0b04c394070f'	System	06 Sep 2020 21:59:45
User entered 'None (0)'	System	06 Sep 2020 21:59:45



US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:53', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff54906-8803-4b9d-901d-0b04c394070f'	System	06 Sep 2020 21:59:45
User entered 'No (N)'	System	06 Sep 2020 21:59:45

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-06T18:01:55', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0ff54906-8803-4b9d-901d-0b04c394070f'	System	06 Sep 2020 21:59:45
User entered '06 Sep 2020 18:01'	System	06 Sep 2020 21:59:45

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Sep 2020 20:53:27
User entered 'Day 7'	System	01 Sep 2020 20:53:27

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:51', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9fcf06fd-88cb-4f41-9ee3-f0fcdc1d07c4'	System	07 Sep 2020 23:13:06
User entered 'None (0)'	System	07 Sep 2020 23:13:06

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:53', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9fcf06fd-88cb-4f41-9ee3-f0fcdc1d07c4'	System	07 Sep 2020 23:13:06
User entered 'None (0)'	System	07 Sep 2020 23:13:06

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:14:56', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9fcf06fd-88cb-4f41-9ee3-f0fcdc1d07c4'	System	07 Sep 2020 23:13:06
User entered 'None (0)'	System	07 Sep 2020 23:13:06



US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:15:02', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9fcf06fd-88cb-4f41-9ee3-f0fcdc1d07c4'	System	07 Sep 2020 23:13:06
User entered 'None (0)'	System	07 Sep 2020 23:13:06

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:15:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9fcf06fd-88cb-4f41-9ee3-f0fcdc1d07c4'	System	07 Sep 2020 23:13:06
User entered 'None (0)'	System	07 Sep 2020 23:13:06

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:15:09', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9fcf06fd-88cb-4f41-9ee3-f0fcdc1d07c4'	System	07 Sep 2020 23:13:06
User entered 'None (0)'	System	07 Sep 2020 23:13:06

US3402153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:42:09

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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:15:13', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9fcf06fd-88cb-4f41-9ee3-f0fc1d07c4'	System	07 Sep 2020 23:13:06
User entered 'No (N)'	System	07 Sep 2020 23:13:06

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-09-07T19:15:14', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '9fcf06fd-88cb-4f41-9ee3-f0fcdc1d07c4'	System	07 Sep 2020 23:13:06
User entered '07 Sep 2020 19:15'	System	07 Sep 2020 23:13:06

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:42:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 20:53:27

**US3402153**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Sep 2020 20:59:51



**US3402153**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '8 Sep 2020'	Traci Hull (b) (4)	08 Sep 2020 20:59:51

**US3402153**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	08 Sep 2020 20:59:51

**US3402153**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Traci Hull (b) (4)	08 Sep 2020 20:59:51

**US3402153**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Sep 2020 21:02:06

**US3402153**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'I'	System	08 Sep 2020 21:02:06

**US3402153**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Sep 2020 12:44:35

**US3402153**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '15 Sep 2020'	Traci Hull (b) (4)	16 Sep 2020 12:44:35

**US3402153**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	16 Sep 2020 12:44:35



US3402153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 12:44:35

US3402153

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Sep 2020 12:44:20

**US3402153**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'I'	System	16 Sep 2020 12:44:20

**US3402153**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	22 Sep 2020 19:06:32

**US3402153**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '22 Sep 2020'	Traci Hull (b) (4)	22 Sep 2020 19:06:32

**US3402153**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	22 Sep 2020 19:06:32

**US3402153**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Traci Hull (b) (4)	22 Sep 2020 19:06:32

**US3402153**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	22 Sep 2020 19:06:36



**US3402153**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'I'	System	22 Sep 2020 19:06:36

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	02 Oct 2020 20:56:19

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '2 Oct 2020'	(b) (4) Traci Hull (b) (4)	02 Oct 2020 20:56:19

US3402153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	02 Oct 2020 20:56:19

US3402153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'VISIT3'	System	02 Oct 2020 20:56:19

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	02 Oct 2020 20:57:09

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '2 Oct 2020'	(b) (4) Traci Hull (b) (4)	02 Oct 2020 20:57:09

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '15:08'	(b) (4) Traci Hull (b) (4)	02 Oct 2020 20:57:09



**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered '2 Oct 2020 15:08'	System	02 Oct 2020 20:57:09

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '36.8' C	(b) (4)	
	Traci Hull (b) (4)	02 Oct 2020 20:57:09
	(b) (4)	

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	02 Oct 2020 20:57:09

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	02 Oct 2020 20:57:09
	(b) (4)	

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '92'	Traci Hull (b) (4)	02 Oct 2020 20:57:09

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'bpm'	System	02 Oct 2020 20:57:09

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '16'	Traci Hull (b) (4)	02 Oct 2020 20:57:09

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'breaths/min'	System	02 Oct 2020 20:57:09



US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '132'	(b) (4) Traci Hull (b) (4)	02 Oct 2020 20:57:09

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'mmHg'	System	02 Oct 2020 20:57:09

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '70'	Traci Hull (b) (4)	02 Oct 2020 20:57:09

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered 'mmHg'	System	02 Oct 2020 20:57:09

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10

US3402153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'No (N)'	(b) (4)	02 Oct 2020 20:57:17
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered empty.	Traci Hull (b) (4)	02 Oct 2020 20:57:17



US3402153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	02 Oct 2020 20:57:31

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '2 Oct 2020'	(b) (4) Traci Hull (b) (4)	02 Oct 2020 20:57:31

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered '15:15'	Traci Hull (b) (4)	02 Oct 2020 20:57:31

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered '2 Oct 2020 15:15'	System	02 Oct 2020 20:57:31

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:54:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	02 Oct 2020 20:56:09

**US3402153**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:10
User entered '1'	System	02 Oct 2020 20:56:09

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 64'	System	01 Aug 2020 18:38:40

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Have you been exposed to someone with 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)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '01 Oct 2020 00:01'	System	01 Aug 2020 18:38:40

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '05 Oct 2020 23:59'	System	01 Aug 2020 18:38:40

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 71'	System	01 Aug 2020 18:38:40

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

[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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-10-08T22:47:47', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '637d9981-9ac4-4bfc-aa3a-6bf50f1c0c8b'	System	09 Oct 2020 02:48:49
User entered 'No (N)'	System	09 Oct 2020 02:48:49

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

Have you been exposed to someone with 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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-10-08T22:47:55', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '637d9981-9ac4-4bfc-aa3a-6bf50f1c0c8b'	System	09 Oct 2020 02:48:49
User entered 'No (N)'	System	09 Oct 2020 02:48:49

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-10-08T22:48:08', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '637d9981-9ac4-4bfc-aa3a-6bf50f1c0c8b'	System	09 Oct 2020 02:48:49
User entered '08 Oct 2020 22:48:08'	System	09 Oct 2020 02:48:49

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '08 Oct 2020 00:01'	System	01 Aug 2020 18:38:40

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '12 Oct 2020 23:59'	System	01 Aug 2020 18:38:40



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 78'	System	01 Aug 2020 18:38:40

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

[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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-10-15T19:51:09', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '245397fc-bf91-490c-90d8-ac55aae17fc0'	System	15 Oct 2020 23:51:57
User entered 'No (N)'	System	15 Oct 2020 23:51:57

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

Have you been exposed to someone with 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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-10-15T19:51:01', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '245397fc-bf91-490c-90d8-ac55aae17fc0'	System	15 Oct 2020 23:51:57
User entered 'No (N)'	System	15 Oct 2020 23:51:57

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-10-15T19:51:21', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '245397fc-bf91-490c-90d8-ac55aae17fc0'	System	15 Oct 2020 23:51:57
User entered '15 Oct 2020 19:51:21'	System	15 Oct 2020 23:51:57

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '15 Oct 2020 00:01'	System	01 Aug 2020 18:38:40

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '19 Oct 2020 23:59'	System	01 Aug 2020 18:38:40

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 92'	System	01 Aug 2020 18:38:40

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Have you been exposed to someone with 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)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '29 Oct 2020 00:01'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '02 Nov 2020 23:59'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 99'	System	01 Aug 2020 18:38:40

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

[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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-11-05T19:30:06', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e2ea2b0f-79ed-488d-a301-73f4421172c2'	System	06 Nov 2020 00:30:48
User entered 'No (N)'	System	06 Nov 2020 00:30:48

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

Have you been exposed to someone with 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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-11-05T19:30:17', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e2ea2b0f-79ed-488d-a301-73f4421172c2'	System	06 Nov 2020 00:30:48
User entered 'No (N)'	System	06 Nov 2020 00:30:48

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-11-05T19:30:22', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e2ea2b0f-79ed-488d-a301-73f4421172c2'	System	06 Nov 2020 00:30:48
User entered '05 Nov 2020 19:30:22'	System	06 Nov 2020 00:30:48

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '05 Nov 2020 00:01'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '09 Nov 2020 23:59'	System	01 Aug 2020 18:38:40



**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 106'	System	01 Aug 2020 18:38:40

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

[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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-11-12T21:07:12', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '76cd772f-a5f7-431a-a88c-832153038cad'	System	13 Nov 2020 02:07:50
User entered 'No (N)'	System	13 Nov 2020 02:07:50

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

Have you been exposed to someone with 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)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-11-12T21:07:23', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '76cd772f-a5f7-431a-a88c-832153038cad'	System	13 Nov 2020 02:07:50
User entered 'No (N)'	System	13 Nov 2020 02:07:50

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-11-12T21:07:27', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '76cd772f-a5f7-431a-a88c-832153038cad'	System	13 Nov 2020 02:07:50
User entered '12 Nov 2020 21:07:27'	System	13 Nov 2020 02:07:50

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '12 Nov 2020 00:01'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:57:11
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '16 Nov 2020 23:59'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03
Data entry locked.	System	01 Aug 2020 18:38:40
User entered 'Day 113'	System	01 Aug 2020 18:38:40

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

[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)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

Have you been exposed to someone with 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)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

US3402153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '19 Nov 2020 00:01'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:25:03
Data entry locked.	System	01 Aug 2020 18:38:40
User entered '23 Nov 2020 23:59'	System	01 Aug 2020 18:38:40

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2020-11-20T16:36:49', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e07d5d14-f794-4050-a234-49a6019ec1c2'	System	20 Nov 2020 21:37:25
User entered 'No (N)'	System	20 Nov 2020 21:37:25

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2020-11-20T16:36:53', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e07d5d14-f794-4050-a234-49a6019ec1c2'	System	20 Nov 2020 21:37:25
User entered 'No (N)'	System	20 Nov 2020 21:37:25

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-11-20T16:37:01', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e07d5d14-f794-4050-a234-49a6019ec1c2'	System	20 Nov 2020 21:37:25
User entered '20 Nov 2020 16:37:01'	System	20 Nov 2020 21:37:25

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2020-11-26T19:00:23', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a84594f2-57ed-49c7-9438-7dc759681f0f'	System	27 Nov 2020 00:00:49
User entered 'No (N)'	System	27 Nov 2020 00:00:49

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2020-11-26T19:00:31', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a84594f2-57ed-49c7-9438-7dc759681f0f'	System	27 Nov 2020 00:00:49
User entered 'No (N)'	System	27 Nov 2020 00:00:49

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-11-26T19:00:35', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a84594f2-57ed-49c7-9438-7dc759681f0f'	System	27 Nov 2020 00:00:49
User entered '26 Nov 2020 19:00:35'	System	27 Nov 2020 00:00:49

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2020-12-03T19:37:50', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a57ec05e-6b47-4c9e-bff2-e4fcc19c5ad7'	System	04 Dec 2020 00:38:10
User entered 'No (N)'	System	04 Dec 2020 00:38:10



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2020-12-03T19:37:55', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a57ec05e-6b47-4c9e-bff2-e4fcc19c5ad7'	System	04 Dec 2020 00:38:10
User entered 'No (N)'	System	04 Dec 2020 00:38:10

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-12-03T19:37:59', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a57ec05e-6b47-4c9e-bff2-e4fcc19c5ad7'	System	04 Dec 2020 00:38:10
User entered '03 Dec 2020 19:37:59'	System	04 Dec 2020 00:38:10

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2020-12-10T19:01:03', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ccb5484-b9f8-4840-93b5-bcc3caec1020'	System	11 Dec 2020 00:01:30
User entered 'No (N)'	System	11 Dec 2020 00:01:30

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2020-12-10T19:01:18', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ccb5484-b9f8-4840-93b5-bcc3caec1020'	System	11 Dec 2020 00:01:30
User entered 'No (N)'	System	11 Dec 2020 00:01:30

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-12-10T19:01:23', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ccbf5484-b9f8-4840-93b5-bcc3caec1020'	System	11 Dec 2020 00:01:30
User entered '10 Dec 2020 19:01:23'	System	11 Dec 2020 00:01:30



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2020-12-18T11:22:40', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c18a347f-75d6-4dab-ab1d-fb4e9b5af1fd'	System	18 Dec 2020 16:22:51
User entered 'No (N)'	System	18 Dec 2020 16:22:51

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2020-12-18T11:22:45', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c18a347f-75d6-4dab-ab1d-fb4e9b5af1fd'	System	18 Dec 2020 16:22:51
User entered 'No (N)'	System	18 Dec 2020 16:22:51

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-12-18T11:22:49', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c18a347f-75d6-4dab-ab1d-fb4e9b5af1fd' User entered '18 Dec 2020 11:22:49'	System	18 Dec 2020 16:22:51
	System	18 Dec 2020 16:22:51

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2020-12-24T19:04:17', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ffa09982-91ef-4f48-8688-a624b6b87db2'	System	25 Dec 2020 00:04:34
User entered 'No (N)'	System	25 Dec 2020 00:04:34

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2020-12-24T19:04:34', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ffa09982-91ef-4f48-8688-a624b6b87db2'	System	25 Dec 2020 00:04:34
User entered 'No (N)'	System	25 Dec 2020 00:04:34

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2020-12-24T19:04:37', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'ffa09982-91ef-4f48-8688-a624b6b87db2'	System	25 Dec 2020 00:04:34
User entered '24 Dec 2020 19:04:37'	System	25 Dec 2020 00:04:34

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-01-07T18:56:07', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '4137ad57-1d5d-44f3-93ac-0eefaa98d314'	System	07 Jan 2021 23:56:10
User entered 'No (N)'	System	07 Jan 2021 23:56:10

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-01-07T18:56:17', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '4137ad57-1d5d-44f3-93ac-0eefaa98d314'	System	07 Jan 2021 23:56:10
User entered 'No (N)'	System	07 Jan 2021 23:56:10

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-07T18:56:22', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '4137ad57-1d5d-44f3-93ac-0eefaa98d314'	System	07 Jan 2021 23:56:10
User entered '07 Jan 2021 18:56:22'	System	07 Jan 2021 23:56:10

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-01-13T13:23:20', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered 'Yes (Y)'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-01-13T13:23:33', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered 'Yes (Y)'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Please 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 (bd047ac41befb604)', Time: '2021-01-13T13:23:46', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-01-13T13:24:16', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered 'Yes (Y)'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '1'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '1'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '1'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '1'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '1'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '1'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '1'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:24:52', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '0'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Please 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 (bd047ac41befb604)', Time: '2021-01-13T13:24:58', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-01-13T13:25:08', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered 'Yes (Y)'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Please 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 (bd047ac41befb604)', Time: '2021-01-13T13:25:11', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 18:25:23



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-13T13:25:31', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'db3035a8-ee3e-4fea-b771-f81c20e0defc'	System	13 Jan 2021 18:25:23
User entered '13 Jan 2021 13:25:31'	System	13 Jan 2021 18:25:23

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-01-20T21:12:37', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f8880853-2fc2-48b7-8f29-aaa11a7e18cc'	System	21 Jan 2021 02:12:30
User entered 'No (N)'	System	21 Jan 2021 02:12:30

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-01-20T21:12:47', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f8880853-2fc2-48b7-8f29-aaa11a7e18cc'	System	21 Jan 2021 02:12:30
User entered 'No (N)'	System	21 Jan 2021 02:12:30

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-20T21:12:50', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'f8880853-2fc2-48b7-8f29-aaa11a7e18cc' User entered '20 Jan 2021 21:12:50'	System	21 Jan 2021 02:12:30
	System	21 Jan 2021 02:12:30

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-01-27T17:20:33', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '788c42b4-a96b-4861-8a83-66e4acabb9f3'	System	27 Jan 2021 22:20:17
User entered 'No (N)'	System	27 Jan 2021 22:20:17

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-01-27T17:20:38', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '788c42b4-a96b-4861-8a83-66e4acabb9f3'	System	27 Jan 2021 22:20:17
User entered 'No (N)'	System	27 Jan 2021 22:20:17

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-01-27T17:20:42', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '788c42b4-a96b-4861-8a83-66e4acabb9f3'	System	27 Jan 2021 22:20:17
User entered '27 Jan 2021 17:20:42'	System	27 Jan 2021 22:20:17

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-02-03T16:38:26', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eb51b00-4faa-464c-a4c1-66b03f4a105e'	System	03 Feb 2021 21:38:09
User entered 'No (N)'	System	03 Feb 2021 21:38:09

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-02-03T16:38:33', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eb51b00-4faa-464c-a4c1-66b03f4a105e'	System	03 Feb 2021 21:38:09
User entered 'No (N)'	System	03 Feb 2021 21:38:09

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-02-03T16:38:37', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1eb51b00-4faa-464c-a4c1-66b03f4a105e'	System	03 Feb 2021 21:38:09
User entered '03 Feb 2021 16:38:37'	System	03 Feb 2021 21:38:09

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-02-10T17:12:25', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e8ef5393-711e-45ef-ac80-7ef8fc3867c6'	System	10 Feb 2021 22:12:12
User entered 'No (N)'	System	10 Feb 2021 22:12:12

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-02-10T17:12:36', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e8ef5393-711e-45ef-ac80-7ef8fc3867c6'	System	10 Feb 2021 22:12:12
User entered 'No (N)'	System	10 Feb 2021 22:12:12



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-02-10T17:12:41', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'e8ef5393-711e-45ef-ac80-7ef8fc3867c6' User entered '10 Feb 2021 17:12:41'	System	10 Feb 2021 22:12:12
	System	10 Feb 2021 22:12:12

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-02-17T13:01:59', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '72664ed0-69b0-4b94-8f8c-d1ef516eb322'	System	17 Feb 2021 18:04:22
User entered 'No (N)'	System	17 Feb 2021 18:04:22

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-02-17T13:02:09', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '72664ed0-69b0-4b94-8f8c-d1ef516eb322'	System	17 Feb 2021 18:04:22
User entered 'No (N)'	System	17 Feb 2021 18:04:22

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-02-17T13:02:12', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '72664ed0-69b0-4b94-8f8c-d1ef516eb322'	System	17 Feb 2021 18:04:22
User entered '17 Feb 2021 13:02:12'	System	17 Feb 2021 18:04:22

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-02-24T16:47:03-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1ff9f6bb-c543-4f50-9f79-f81073849b97'	System	24 Feb 2021 21:46:40
User entered 'No (N)'	System	24 Feb 2021 21:46:40

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-02-24T16:47:12-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1ff9f6bb-c543-4f50-9f79-f81073849b97'	System	24 Feb 2021 21:46:40
User entered 'No (N)'	System	24 Feb 2021 21:46:40

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-02-24T16:47:16-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '1ff9f6bb-c543-4f50-9f79-f81073849b97'	System	24 Feb 2021 21:46:40
User entered '24 Feb 2021 16:47:16'	System	24 Feb 2021 21:46:40

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-03-03T12:28:18-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3037b5ee-a758-4812-af85-319796be4f8f'	System	03 Mar 2021 20:05:21
User entered 'No (N)'	System	03 Mar 2021 20:05:21

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-03-03T12:28:23-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3037b5ee-a758-4812-af85-319796be4f8f'	System	03 Mar 2021 20:05:21
User entered 'No (N)'	System	03 Mar 2021 20:05:21

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-03T12:28:26-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '3037b5ee-a758-4812-af85-319796be4f8f' User entered '03 Mar 2021 12:28:26'	System	03 Mar 2021 20:05:21
	System	03 Mar 2021 20:05:21

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-03-09T16:47:54-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c0b26a28-d4c5-4140-9305-9abc549d43df'	System	09 Mar 2021 21:47:21
User entered 'No (N)'	System	09 Mar 2021 21:47:21

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-03-09T16:47:59-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c0b26a28-d4c5-4140-9305-9abc549d43df'	System	09 Mar 2021 21:47:21
User entered 'No (N)'	System	09 Mar 2021 21:47:21



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-09T16:48:03-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'c0b26a28-d4c5-4140-9305-9abc549d43df' User entered '09 Mar 2021 16:48:03'	System	09 Mar 2021 21:47:21
	System	09 Mar 2021 21:47:21

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-03-15T15:19:21-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered 'Yes (Y)'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-03-15T15:19:30-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered 'No (N)'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-03-15T15:19:38-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered 'Yes (Y)'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '1'	System	15 Mar 2021 19:19:31



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered '1'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '1'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered '1'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered '1'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered '1'	System	15 Mar 2021 19:19:31



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '0'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:19:57-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered '0'	System	15 Mar 2021 19:19:31



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Please 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 (bd047ac41befb604)', Time: '2021-03-15T15:20:04-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-03-15T15:20:09-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358'	System	15 Mar 2021 19:19:31
User entered 'No (N)'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-15T15:20:12-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'a638f06a-b75d-42e4-b2a0-2081b9334358' User entered '15 Mar 2021 15:20:12'	System	15 Mar 2021 19:19:31

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-03-22T15:33:27-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'd144c14c-cd8a-4c23-92bb-f174adf4dd93'	System	22 Mar 2021 19:33:09
User entered 'No (N)'	System	22 Mar 2021 19:33:09

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-03-22T15:33:34-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'd144c14c-cd8a-4c23-92bb-f174adf4dd93'	System	22 Mar 2021 19:33:09
User entered 'No (N)'	System	22 Mar 2021 19:33:09



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-22T15:34:06-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'd144c14c-cd8a-4c23-92bb-f174adf4dd93'	System	22 Mar 2021 19:33:09
User entered '22 Mar 2021 15:34:06'	System	22 Mar 2021 19:33:09

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-03-30T18:16:02-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'eb1398ae-f9ea-4569-9ec8-df091b2182bb'	System	30 Mar 2021 22:15:13
User entered 'No (N)'	System	30 Mar 2021 22:15:13

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-03-30T18:16:10-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'eb1398ae-f9ea-4569-9ec8-df091b2182bb'	System	30 Mar 2021 22:15:13
User entered 'No (N)'	System	30 Mar 2021 22:15:13

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-30T18:16:13-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'eb1398ae-f9ea-4569-9ec8-df091b2182bb'	System	30 Mar 2021 22:15:13
User entered '30 Mar 2021 18:16:13'	System	30 Mar 2021 22:15:13

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-04-05T14:22:22-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0d0074e1-e0af-4e00-9e06-9ef0489005ce' User entered 'No (N)'	System	05 Apr 2021 18:21:36
	System	05 Apr 2021 18:21:36

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-04-05T14:22:31-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0d0074e1-e0af-4e00-9e06-9ef0489005ce'	System	05 Apr 2021 18:21:36
User entered 'No (N)'	System	05 Apr 2021 18:21:36

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-04-05T14:22:36-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '0d0074e1-e0af-4e00-9e06-9ef0489005ce' User entered '05 Apr 2021 14:22:36'	System	05 Apr 2021 18:21:36
	System	05 Apr 2021 18:21:36

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-04-12T16:27:04-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '021d29a2-51aa-4007-9871-5d9977e7118f' User entered 'No (N)'	System	12 Apr 2021 20:26:01
	System	12 Apr 2021 20:26:01

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-04-12T16:27:07-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '021d29a2-51aa-4007-9871-5d9977e7118f' User entered 'No (N)'	System	12 Apr 2021 20:26:01
	System	12 Apr 2021 20:26:01

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-04-12T16:27:10-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '021d29a2-51aa-4007-9871-5d9977e7118f'	System	12 Apr 2021 20:26:01
User entered '12 Apr 2021 16:27:10'	System	12 Apr 2021 20:26:01

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-04-19T16:49:50-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'dc61825e-3947-4c8b-9a89-bb2ae806799d'	System	19 Apr 2021 20:48:45
User entered 'No (N)'	System	19 Apr 2021 20:48:45

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-04-19T16:49:55-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'dc61825e-3947-4c8b-9a89-bb2ae806799d'	System	19 Apr 2021 20:48:45
User entered 'No (N)'	System	19 Apr 2021 20:48:45



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-04-19T16:49:59-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'dc61825e-3947-4c8b-9a89-bb2ae806799d'	System	19 Apr 2021 20:48:45
User entered '19 Apr 2021 16:49:59'	System	19 Apr 2021 20:48:45

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-04-26T14:37:16-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'fb80cb0e-6285-4ffc-92ce-c1ac8d453dd8'	System	26 Apr 2021 18:36:08
User entered 'No (N)'	System	26 Apr 2021 18:36:08

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-04-26T14:37:20-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'fb80cb0e-6285-4ffc-92ce-c1ac8d453dd8'	System	26 Apr 2021 18:36:08
User entered 'No (N)'	System	26 Apr 2021 18:36:08

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-04-26T14:37:23-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: 'fb80cb0e-6285-4ffc-92ce-c1ac8d453dd8'	System	26 Apr 2021 18:36:08
User entered '26 Apr 2021 14:37:23'	System	26 Apr 2021 18:36:08

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[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 (bd047ac41befb604)', Time: '2021-05-03T08:32:38-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '15806c80-ae71-4b7c-9de9-edb29cb67bae'	System	03 May 2021 12:31:54
User entered 'No (N)'	System	03 May 2021 12:31:54

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

Have you been exposed to someone with 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 (bd047ac41befb604)', Time: '2021-05-03T08:33:03-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '15806c80-ae71-4b7c-9de9-edb29cb67bae'	System	03 May 2021 12:31:54
User entered 'No (N)'	System	03 May 2021 12:31:54

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-05-03T08:33:14-04:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '15806c80-ae71-4b7c-9de9-edb29cb67bae'	System	03 May 2021 12:31:54
User entered '03 May 2021 08:33:14'	System	03 May 2021 12:31:54

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:25:03



**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 11:25:03

**US3402153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:42:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:25:03
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 11:25:03

US3402153

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:42:09

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)	26 Apr 2021 06:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-03T15:04:31-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '67534f84-9710-4bad-8871-1ea8522efd64'	System	03 Mar 2021 20:05:41
User entered 'No (N)'	System	03 Mar 2021 20:05:41

**US3402153**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:35:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bd047ac41befb604)', Time: '2021-03-03T15:04:37-05:00', User OID: 'PatientReportedOutcome (US3402153)', ODM File OID: '67534f84-9710-4bad-8871-1ea8522efd64'	System	03 Mar 2021 20:05:41
User entered '03 Mar 2021 15:04:37'	System	03 Mar 2021 20:05:41

**US3402153**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:17:15
User entered 'Yes (Y)'	Traci Hull (b) (4)	26 Oct 2020 17:25:30



**US3402153**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:17:15
User entered '26 Oct 2020'	Traci Hull (b) (4)	26 Oct 2020 17:25:30

**US3402153**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:17:15
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	26 Oct 2020 17:25:30

**US3402153**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:17:15
User entered empty.	Traci Hull (b) (4)	26 Oct 2020 17:25:30

**US3402153**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:17:15
User entered 'Yes (Y)'	Traci Hull (b) (4)	26 Oct 2020 17:25:18

US3402153

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:39:09
User entered 'I'	System	26 Oct 2020 17:25:18

**US3402153**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	30 Nov 2020 20:01:31

**US3402153**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered '30 Nov 2020'	Traci Hull (b) (4)	30 Nov 2020 20:01:31

**US3402153**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	30 Nov 2020 20:01:31



**US3402153**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	30 Nov 2020 20:01:31
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	30 Nov 2020 20:01:22

**US3402153**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User entered 'I'	System	30 Nov 2020 20:01:22

**US3402153**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4)	28 Dec 2020 18:03:20
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered '28 Dec 2020'	(b) (4) Traci Hull (b) (4)	28 Dec 2020 18:03:20

**US3402153**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	28 Dec 2020 18:03:20

**US3402153**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	28 Dec 2020 18:03:20
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Dec 2020 18:03:10



**US3402153**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User entered 'I'	System	28 Dec 2020 18:03:10

**US3402153**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	02 Feb 2021 17:51:22

**US3402153**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered '29 Jan 2021'	Traci Hull (b) (4)	02 Feb 2021 17:51:22

**US3402153**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	02 Feb 2021 17:51:22

**US3402153**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	02 Feb 2021 17:51:22
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	02 Feb 2021 17:51:11

**US3402153**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:29:15
User entered 'I'	System	02 Feb 2021 17:51:11

US3402153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User closed query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 9 Mar 2021, however, 'Were vital signs assessed?' is not completed at this visit but at Participant Decision Visit / OL-D1 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the assessment data should be entered at both visits per sponsor. Please review and update as appropriate. Thank You! ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:18:46
Query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 9 Mar 2021, however, 'Were vital signs assessed?' is not completed at this visit but at Participant Decision Visit / OL-D1 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the assessment data should be entered at both visits per sponsor. Please review and update as appropriate. Thank You! ' answered with 'updated ' (Site from DM).	Traci Hull (b) (4) (b) (4)	30 Mar 2021 19:08:00
User opened query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 9 Mar 2021, however, 'Were vital signs assessed?' is not completed at this visit but at Participant Decision Visit / OL-D1 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the assessment data should be entered at both visits per sponsor. Please review and update as appropriate. Thank You! ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:04:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	09 Mar 2021 21:24:52



**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered '09 Mar 2021'	(b) (4)	09 Mar 2021 21:24:52
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Mar 2021 21:24:52

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'VISIT4'	System	09 Mar 2021 21:24:52

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'No (N)'	Traci Hull (b) (4)	30 Mar 2021 19:07:11

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	30 Mar 2021 19:07:11
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 19:07:11

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	30 Mar 2021 19:07:11

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	30 Mar 2021 19:07:11
	Traci Hull (b) (4)	
	(b) (4)	



**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	30 Mar 2021 19:07:11
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	30 Mar 2021 19:07:11
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 19:07:11

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	30 Mar 2021 19:07:11

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	30 Mar 2021 19:07:11
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	30 Mar 2021 19:07:11

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	30 Mar 2021 19:07:11
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	30 Mar 2021 19:07:11



**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	30 Mar 2021 19:07:11
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered empty.	System	30 Mar 2021 19:07:11

US3402153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Mar 2021 21:25:30
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:25:08
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty; reason for change Data Entry Error	Traci Hull (b) (4)	09 Mar 2021 21:25:30
User entered '09 Mar 2021'	Traci Hull (b) (4)	09 Mar 2021 21:25:08

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	09 Mar 2021 21:25:59

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered '09 Mar 2021'	(b) (4)	09 Mar 2021 21:25:59
	Traci Hull (b) (4)	
	(b) (4)	



**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered '15:17'	(b) (4)	09 Mar 2021 21:25:59
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered '09 Mar 2021 15:17'	System	09 Mar 2021 21:25:59

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4)	09 Mar 2021 21:26:03
	Traci Hull (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:47
User entered 'I'	System	09 Mar 2021 21:26:03

**US3402153**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	29 Mar 2021 19:52:48
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '29 Mar 2021'	Traci Hull (b) (4)	29 Mar 2021 19:52:48
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	29 Mar 2021 19:52:48

**US3402153**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	29 Mar 2021 19:52:48
	(b) (4)	



**US3402153**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	29 Mar 2021 19:52:51
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:52:51

**US3402153**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 May 2021 12:18:29
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered '29 Apr 2021'	Traci Hull (b) (4)	03 May 2021 12:18:29
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 May 2021 12:18:29

**US3402153**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:18:29
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 May 2021 12:18:37
	(b) (4)	

**US3402153**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 12:18:37



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:13:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:23:01
User entered '13 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	09 Feb 2021 14:10:53
User entered '15 Jan 2021'	(b) (4) Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:26:47

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:42:09**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:13:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:23:01
User entered '12:00'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:26:47

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:42:09**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:13:49
User entered '13 Jan 2021 12:00'	System	09 Feb 2021 14:10:53
User entered '15 Jan 2021 12:00'	System	18 Jan 2021 19:26:47

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:42:09**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:13:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:23:01
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:26:47

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:42:09**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:13:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:23:01
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:26:47

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
Query 'Per CDM: Per sponsor review, please verify data for duplicate Dates, since there are 2 forms with 'Date' recorded as '13Jan2021'. If duplicate, please remove the data on this form, and confirm the form can be inactivated. Then update the rest of 'Symptom Days' to follow in sequence with this update, else clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Mar 2021 19:38:28
User opened query 'Per CDM: Per sponsor review, please verify data for duplicate Dates, since there are 2 forms with 'Date' recorded as '13Jan2021'. If duplicate, please remove the data on this form, and confirm the form can be inactivated. Then update the rest of 'Symptom Days' to follow in sequence with this update, else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 19:38:11
User entered 'Day 1 (Day 1)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User closed query ' Per CDM: Per sponsor review, please verify data for duplicate Dates, since there are 2 forms with 'Date' recorded as '13Jan2021'. If duplicate, please remove the data on this form, and confirm the form can be inactivated. Then update the rest of 'Symptom Days' to follow in sequence with this update, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:20:46
Query ' Per CDM: Per sponsor review, please verify data for duplicate Dates, since there are 2 forms with 'Date' recorded as '13Jan2021'. If duplicate, please remove the data on this form, and confirm the form can be inactivated. Then update the rest of 'Symptom Days' to follow in sequence with this update, else clarify.' answered with 'UPDATED DATE TO REFLECT THE DATE THE SYMPTOMS BEGAN' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:16:08
User entered '10 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:15:50
User opened query ' Per CDM: Per sponsor review, please verify data for duplicate Dates, since there are 2 forms with 'Date' recorded as '13Jan2021'. If duplicate, please remove the data on this form, and confirm the form can be inactivated. Then update the rest of 'Symptom Days' to follow in sequence with this update, else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 19:38:35
User entered '13 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 18:56:56
User entered '10 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '1' reason for change: New Information	Traci Hull (b) (4)	22 Jan 2021 15:50:03
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16



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Form: Symptom Log (1)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User closed query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 15:34:31
Query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' answered with 'updated ' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 18:49:15
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 18:48:46
User opened query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:14:58
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered empty.	System	05 Mar 2021 18:48:46
User entered '%'	System	18 Jan 2021 19:28:16

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User closed query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 15:34:42
Query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' answered with 'updated ' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 18:49:21
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 18:48:46
User opened query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:15:06
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16



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Form: Symptom Log (1)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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**Form: Symptom Log (1)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16



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Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Form: Symptom Log (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Form: Symptom Log (1)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:50:03
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:16

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 2 (Day 2)'	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 19:29:06

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '11 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '1' reason for change: New Information	Traci Hull (b) (4)	22 Jan 2021 15:51:27
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Form: Symptom Log (2)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User closed query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 15:35:13
Query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' answered with 'UPDATED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:09:50
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:09:37
User opened query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:15:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered empty.	System	05 Mar 2021 20:09:37
User entered '%'	System	18 Jan 2021 19:31:48
User entered empty.	System	18 Jan 2021 19:29:06



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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User closed query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 15:35:25
Query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' answered with 'UPDATED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:09:54
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:09:37
User opened query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:15:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Form: Symptom Log (2)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Form: Symptom Log (2)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06



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Form: Symptom Log (2)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:51:27
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 3 (Day 3)'	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '12 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '1' reason for change: New Information	Traci Hull (b) (4)	22 Jan 2021 15:52:57
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User closed query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 15:35:47
Query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' answered with 'UPDATED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:10:19
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:10:13
User opened query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:16:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered empty.	System	05 Mar 2021 20:10:13
User entered '%'	System	18 Jan 2021 19:31:48
User entered empty.	System	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User closed query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 15:36:04
Query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' answered with 'UPDATED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:10:23
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:10:13
User opened query 'Please leave this field blank because "Assessment Not Done" was check above. It covers the entire page.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:16:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered empty; reason for change New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:52:57
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:29:06

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User closed query 'Per sponsor review, 'Symptom Days' are out of sequence starting on 13Jan2021. Please review data and consider updating to 'Day 1' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 09:21:03
Query 'Per sponsor review, 'Symptom Days' are out of sequence starting on 13Jan2021. Please review data and consider updating to 'Day 1' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' answered with 'DATA IS CORRECT THE 13TH WOULD BE THE 4TH DAY OF SYMPTOMS' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:16:43
User opened query 'Per sponsor review, 'Symptom Days' are out of sequence starting on 13Jan2021. Please review data and consider updating to 'Day 1' on this form. Then update the rest of 'Symptom Days' to follow in sequence with this update, or please clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 19:39:20
User entered 'Day 4 (Day 4)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '13 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98' reason for change: New Information	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:54:11
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	18 Jan 2021 19:31:48

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '37.9' C reason for change: New Information	Traci Hull (b) (4)	22 Jan 2021 15:54:11
User entered missing code ND - Not Done.	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 19:31:48
	(b) (4)	

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:31:48

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 5 (Day 5)'	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 19:33:34

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '14 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98' reason for change: New Information	Traci Hull (b) (4)	20 Jan 2021 15:54:17
User entered missing code ND - Not Done.	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 19:33:34
	(b) (4)	

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	18 Jan 2021 19:33:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '99.1' F reason for change: New Information	Traci Hull (b) (4)	20 Jan 2021 15:54:17
User entered missing code ND - Not Done.	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 19:33:34
	(b) (4)	

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:54:17
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:54:17
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:54:17
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:54:17
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 6 (Day 6)'	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '15 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97' reason for change: New Information	Traci Hull (b) (4)	20 Jan 2021 15:56:19
User entered '98'	(b) (4) Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	18 Jan 2021 19:33:34



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '99.0' F reason for change: New Information	Traci Hull (b) (4)	20 Jan 2021 15:56:19
User entered '37.9' C	(b) (4) Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:56:19
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:56:19
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:56:19
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:56:19
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:56:19
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:56:19
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:56:19
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:33:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 7 (Day 7)'	(b) (4) Traci Hull (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '16 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '99.0' F	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:02

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 8 (Day 8)'	(b) (4) Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '17 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '96'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	20 Jan 2021 15:57:46

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '99.0' F	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:57:46

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 9 (Day 9)'	(b) (4) Traci Hull (b) (4)	20 Jan 2021 15:59:02

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '18 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '94' reason for change: New Information	Traci Hull (b) (4)	22 Jan 2021 15:47:32
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	20 Jan 2021 15:59:02
	(b) (4)	

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	20 Jan 2021 15:59:02

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '99.8' F reason for change: New Information	Traci Hull (b) (4)	22 Jan 2021 15:47:32
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	20 Jan 2021 15:59:02
	(b) (4)	

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 15:59:02

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 10 (Day 10)'	(b) (4) Traci Hull (b) (4)	20 Jan 2021 16:00:07

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '89'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	20 Jan 2021 16:00:07



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '100.2' F	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:00:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 11 (Day 11)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 12:38:14

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '20 Jan 2021'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	22 Jan 2021 12:38:14

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '100.0' F	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14



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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 12:38:14

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 12 (Day 12)'	(b) (4) Traci Hull (b) (4)	23 Jan 2021 13:25:12



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '21 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:56:34
User entered '23 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	23 Jan 2021 13:25:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '96.7' F	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 13 (Day 13)'	(b) (4) Traci Hull (b) (4)	23 Jan 2021 13:25:43

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '22 Jan 2021'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43



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Form: Symptom Log (13)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '96'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	23 Jan 2021 13:25:43

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98.4' F	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (13)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43



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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:25:43

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 14 (Day 14)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 13:06:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:42:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '23 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '93'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	26 Jan 2021 13:06:20



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.9' F	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20



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Form: Symptom Log (14)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (14)**

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20



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**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:06:20

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 15 (Day 15)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 13:08:15

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '24 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '93'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98.6' F	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15



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**Form: Symptom Log (15)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Form: Symptom Log (15)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:08:15

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 16 (Day 16)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 13:10:23
	(b) (4)	



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '25 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '92'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	26 Jan 2021 13:10:23

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.6' F	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23



US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (16)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:10:23

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 17 (Day 17)'	(b) (4) Traci Hull (b) (4)	27 Jan 2021 12:57:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	27 Jan 2021 12:57:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98.6' F	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:42:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50



US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:57:50

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 18 (Day 18)'	(b) (4) Tammy Kohn (b) (4)	28 Jan 2021 15:30:30

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '27 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	28 Jan 2021 15:30:30



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.9' F	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4)	28 Jan 2021 15:30:30
	(b) (4)	

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (18)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (18)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 15:30:30

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 19 (Day 19)'	(b) (4) Tammy Kohn (b) (4)	30 Jan 2021 13:07:37

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '28 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '93'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	30 Jan 2021 13:07:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.9' F	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:07:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 20 (Day 20)'	(b) (4) Tammy Kohn (b) (4)	30 Jan 2021 13:09:36



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '29 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '95'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	30 Jan 2021 13:09:36

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.7' F	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (20)**

**Generated On: 11 Aug 2021 22:42:09**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 13:09:36

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 21 (Day 21)'	(b) (4) Traci Hull (b) (4)	02 Feb 2021 13:27:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '30 Jan 2021'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	02 Feb 2021 13:27:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.9' F	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 22:42:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (21)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (21)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:27:45

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 22 (Day 22)'	(b) (4) Traci Hull (b) (4)	02 Feb 2021 13:28:33

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '31 Jan 2021'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '96'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	02 Feb 2021 13:28:33



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.8' F	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (22)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:28:33

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 23 (Day 23)'	(b) (4) Traci Hull (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '1 Feb 2021'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '96'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	02 Feb 2021 13:29:01

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.4' F	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (23)**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:29:01

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 24 (Day 24)'	(b) (4) Traci Hull (b) (4)	03 Feb 2021 13:24:12



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '2 Feb 2021'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '95'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.3' F	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (24)**

**Generated On: 11 Aug 2021 22:42:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

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**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12



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Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (24)**

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:24:12

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 25 (Day 25)'	(b) (4) Traci Hull (b) (4)	04 Feb 2021 14:49:54

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '3 Feb 2021'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '96'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	04 Feb 2021 14:49:54

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98.0' F	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (25)**

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54



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Form: Symptom Log (25)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (25)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Form: Symptom Log (25)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54



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Form: Symptom Log (25)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:49:54

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 26 (Day 26)'	(b) (4) Tammy Kohn (b) (4)	05 Feb 2021 15:38:19

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '4 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '95'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	05 Feb 2021 15:38:19



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98.3' F	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (26)**

**Generated On: 11 Aug 2021 22:42:09**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	05 Feb 2021 15:38:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 27 (Day 27)'	(b) (4) Traci Hull (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User closed query 'Per CDM: Per sponsor review, please verify and consider updating 'Date' to 05Feb2021' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:21:24
Query 'Per CDM: Per sponsor review, please verify and consider updating 'Date' to 05Feb2021' answered with 'DATE CORRECTED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:17:28
User entered '5 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Mar 2021 19:17:16
User opened query 'Per CDM: Per sponsor review, please verify and consider updating 'Date' to 05Feb2021' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 19:33:41
User entered '8 Feb 2021'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '96'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	08 Feb 2021 13:20:20

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98.6' F	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 22:42:09**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (27)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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**Form: Symptom Log (27)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:20:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 28 (Day 28)'	(b) (4) Traci Hull (b) (4)	08 Feb 2021 19:44:13



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '6 Feb 2021'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	08 Feb 2021 19:44:13

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98.7' F	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13



US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 22:42:09**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (28)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:13

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 29 (Day 29)'	(b) (4) Traci Hull (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '7 Feb 2021'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '96'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	08 Feb 2021 19:44:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '98.4' F	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45



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Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (29)**

**Generated On: 11 Aug 2021 22:42:09**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (29)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Feb 2021 19:44:45

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User entered 'Day 30 (Day 30)'	(b) (4) Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '8 Feb 2021'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '0'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User entered '%'	System	09 Feb 2021 13:34:50



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered '97.5' F	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50



US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (30)**

**Generated On: 11 Aug 2021 22:42:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (30)

Generated On: 11 Aug 2021 22:42:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:34:50

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:09
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:18:08
User entered '13 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	09 Feb 2021 14:10:29
User entered '15 Jan 2021'	(b) (4) Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:38

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:42:09**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:09
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:18:13
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:38

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:42:09

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:09
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:22:38
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)	03 Mar 2021 11:25:34
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 'Correct as is' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	02 Mar 2021 15:50:07
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	02 Mar 2021 15:49:52
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	02 Mar 2021 15:49:52
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	02 Mar 2021 15:49:52
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:18:18
User closed query 'Per ETRTR: Please confirm answer upon NP Swab test results on 13Jan21, thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 18:18:02
Query 'Per ETRTR: Please confirm answer upon NP Swab test results on 13Jan21, thanks.' answered with 'data updated' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	09 Feb 2021 14:11:47
User opened query 'Per ETRTR: Please confirm answer upon NP Swab test results on 13Jan21, thanks.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 21:52:48
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).	System	19 Jan 2021 21:02:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:42:09

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
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 by data change (Site from System).	System	19 Jan 2021 21:02:48
User entered 'No (N)' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 21:02:48
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	18 Jan 2021 21:24:30
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:24:30
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:38

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Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:42:09

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:09
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 08:34:20
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'updated dates of illness visit to match the 13 JAN 2021 DATE ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 18:59:12
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:40:08
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:18:22
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "15-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "13-JAN-2021" for Illness visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:50:42
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "15-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "13-JAN-2021" for Illness visit. Kindly review the collection date and update as appropriate, else clarify. ' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Feb 2021 14:11:50
User entered '13 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Feb 2021 14:10:29

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "15-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "13-JAN-2021" for Illness visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM). User entered '15 Jan 2021'	(b) (4), (b) (6)	08 Feb 2021 07:30:18
	Tammy Kohn (b) (4)	18 Jan 2021 19:28:38
	(b) (4)	

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:42:09

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:09
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:18:27
User entered 'Nasal Swab (Nasal Swab)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:38



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID Diagnostic Test**

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:09
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:18:30
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:38

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:42:09**

[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)	02 May 2021 23:14:09
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:18:35
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:38

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID Diagnostic Test**

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:09
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:18:40
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:38

**US3402153**

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**Form: COVID Diagnostic Test**

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:09
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:18:45
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:28:38

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Form: COVID Diagnostic Test

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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:09
User entered '1'	System	02 Mar 2021 15:49:52
User entered '0'	System	19 Jan 2021 21:02:48
User entered '1'	System	18 Jan 2021 21:24:30
User entered '0'	System	18 Jan 2021 19:28:38

US3402153

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:42:09

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:56
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:25:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:56
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:56
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:25:12



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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:56
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:25:12

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Did the subject have Heart Rate  \$\geq\$  125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:56
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
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[Heart Rate](#)

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

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[Oxygen Saturation](#)

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

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[PaO2](#)

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[Did the subject have Respiratory failure?](#)

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

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[High-Flow Oxygen?](#)

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[Non-Invasive Ventilation?](#)

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[Mechanical Ventilation?](#)

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[ECMO?](#)

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**Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg**

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[Evidence of Shock Requires  
Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Radiographical Evidence](#)

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**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:56
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:56
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:56
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:25:12

**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:00:56
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:25:12



**US3402153**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:14:22
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:22:21
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:26:51

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

US3402153

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:42:09

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:27:52
User closed query 'Per Lab Recon: Saliva: It appears there is a collection date mismatch between EDC & PPD GCL records for this sample, as the "date of collection" is recorded as "15 JAN 2021" in EDC, however the same is recorded as "14 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you.	(b) (4), (b) (6)	24 Feb 2021 06:27:17
' (Site from DM).		
Query 'Per Lab Recon: Saliva: It appears there is a collection date mismatch between EDC & PPD GCL records for this sample, as the "date of collection" is recorded as "15 JAN 2021" in EDC, however the same is recorded as "14 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you.	Tammy Kohn (b) (4)	23 Feb 2021 19:38:58
	(b) (4)	
' answered with 'DATA UPDATED' (Site from DM).		
User opened query 'Per Lab Recon: Saliva: It appears there is a collection date mismatch between EDC & PPD GCL records for this sample, as the "date of collection" is recorded as "15 JAN 2021" in EDC, however the same is recorded as "14 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you.	(b) (4), (b) (6)	10 Feb 2021 09:48:50
' (Site from DM).		
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	02 Feb 2021 13:31:24
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Tammy Kohn (b) (4)	29 Jan 2021 21:25:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	25 Jan 2021 14:40:09
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	23 Jan 2021 13:27:54
	(b) (4)	

US3402153

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:42:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered '14 Jan 2021' reason for change: New Information	Tammy Kohn (b) (4)	23 Feb 2021 19:38:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:12:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 21:25:15
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:07:34
User entered '15 Jan 2021' reason for change: New Information	Traci Hull (b) (4)	25 Jan 2021 14:40:09
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

US3402153

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:42:09

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:27:52
User closed query 'Per Lab Recon: Saliva: It appears there is a collection date mismatch between EDC & PPD GCL records for this sample, as the "date of collection" is recorded as "17 JAN 2021" in EDC, however the same is recorded as "16 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 06:27:22
Query 'Per Lab Recon: Saliva: It appears there is a collection date mismatch between EDC & PPD GCL records for this sample, as the "date of collection" is recorded as "17 JAN 2021" in EDC, however the same is recorded as "16 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	23 Feb 2021 19:39:30
User opened query 'Per Lab Recon: Saliva: It appears there is a collection date mismatch between EDC & PPD GCL records for this sample, as the "date of collection" is recorded as "17 JAN 2021" in EDC, however the same is recorded as "16 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 09:50:10
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	02 Feb 2021 13:31:24
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Tammy Kohn (b) (4)	29 Jan 2021 21:25:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	25 Jan 2021 14:40:09
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	23 Jan 2021 13:27:54
	(b) (4)	

US3402153

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:42:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered '16 Jan 2021' reason for change: New Information	Tammy Kohn (b) (4)	23 Feb 2021 19:39:24
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4)	
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 21:25:22
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:07:43
User entered '17 Jan 2021' reason for change: New Information	Traci Hull (b) (4)	25 Jan 2021 14:40:09
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54



**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	02 Feb 2021 13:31:24
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Tammy Kohn (b) (4)	29 Jan 2021 21:25:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	25 Jan 2021 14:40:09
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	23 Jan 2021 13:27:54
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:42:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:27:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:12:27
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4)	29 Jan 2021 21:25:30
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:07:55
User entered '19 Jan 2021' reason for change: New Information	Traci Hull (b) (4)	25 Jan 2021 14:40:09
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	23 Jan 2021 13:27:54
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	02 Feb 2021 13:31:24
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 21:25:08
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

US3402153

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:42:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:27:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:12:32
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4)	29 Jan 2021 21:25:37
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:08:02
User entered '21 Jan 2021'	Traci Hull (b) (4)	23 Jan 2021 13:27:54
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	02 Feb 2021 13:31:24
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Tammy Kohn (b) (4)	29 Jan 2021 21:25:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	27 Jan 2021 13:01:16
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	23 Jan 2021 13:27:54
	(b) (4)	

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered '26 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	27 Jan 2021 13:01:16
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54



**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:27:31
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered '2 Feb 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	08 Feb 2021 13:27:31
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 19:36:25
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:52
User entered '09 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Feb 2021 19:36:25
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	23 Jan 2021 13:27:54

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:23:25
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	18 Jan 2021 19:34:00

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	22 Apr 2021 02:23:25
User entered '13 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Mar 2021 18:40:58
User entered '15 Jan 2021'	(b) (4)	18 Jan 2021 19:34:00



**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	22 Apr 2021 02:23:25
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4)	18 Jan 2021 19:34:00

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User entered 'SICKD1'	System	18 Jan 2021 19:34:00

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52

US3402153

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:07:55
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Mar 2021 18:41:15
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	05 Mar 2021 18:41:15
User entered '13 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 18:41:15
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Mar 2021 18:40:58
User entered '15 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:34:52

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	23 Apr 2021 22:07:55
User entered '12:13'	(b) (4), (b) (6)	
	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52
	(b) (4)	

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User entered '13 Jan 2021 12:13'	System	05 Mar 2021 18:41:15
User entered '15 Jan 2021 12:13'	System	18 Jan 2021 19:34:52

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 22:07:55
User entered missing code ND - Not Done.	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52
DataPoint set to visible.	(b) (4)	
	System	18 Jan 2021 19:34:00

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:07:55
User entered missing code ND - Not Done.	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52
DataPoint set to visible.	(b) (4) System	18 Jan 2021 19:34:00



**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '37.9' C	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52
	(b) (4)	

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 22:07:55
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52
	(b) (4)	

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 22:07:55
User entered '96'	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52
	(b) (4)	

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User entered 'bpm'	System	18 Jan 2021 19:34:52

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '16'	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User entered 'breaths/min'	System	18 Jan 2021 19:34:52

US3402153

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '123'	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52
	(b) (4)	



**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User entered 'mmHg'	System	18 Jan 2021 19:34:52

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '82'	Tammy Kohn (b) (4)	18 Jan 2021 19:34:52
	(b) (4)	

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User entered 'mmHg'	System	18 Jan 2021 19:34:52

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37

**US3402153**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	23 Apr 2021 22:08:03
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	18 Jan 2021 19:34:58
	(b) (4)	

US3402153

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:08:03
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Mar 2021 18:41:21
User entered '13 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 18:41:21
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Mar 2021 18:40:58
User entered '15 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:34:58

US3402153

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:42:09

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:23:43
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 09 FEB 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:17:41
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 09 FEB 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'UPDATED DAY 28 ADDED 09 FEB 2021' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 19:37:13
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 09 FEB 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:38:06
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:35:06



US3402153

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:42:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:23:43
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 13JAN2021 is reported under illness visit Day 1 in EDC, however the SARS-CoV-2 serum sample dated 15JAN2021 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:27:46
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 13JAN2021 is reported under illness visit Day 1 in EDC, however the SARS-CoV-2 serum sample dated 15JAN2021 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' answered with 'Requisition ID:1F640635947 IN PPD IS DATED 13JAN2021' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 19:42:47
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 13JAN2021 is reported under illness visit Day 1 in EDC, however the SARS-CoV-2 serum sample dated 15JAN2021 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:03:41
User entered '13 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 18:41:30
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 15 JAN 2021 is reported under illness visit Day 1 in EDC, however the sample dated 13 JAN 2021 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 06:29:17

US3402153

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:42:09

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 15 JAN 2021 is reported under illness visit Day 1 in EDC, however the sample dated 13 JAN 2021 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'THE 13TH IS INCORRECT AS THE SUBJECT DID NOT COME IN FOR THE ILLNESS VISIT UNTIL 15 JAN 2021' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 13:07:14
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 15 JAN 2021 is reported under illness visit Day 1 in EDC, however the sample dated 13 JAN 2021 is reported under illness visit Day 1 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	04 Feb 2021 07:36:14
Query 'Per Lab Recon: SARS-COV2: Sample dated 15 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	04 Feb 2021 07:35:23
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 15 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Jan 2021 11:16:16
User entered '15 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 19:35:06

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	22 Apr 2021 02:26:59
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	23 Feb 2021 19:33:38

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	22 Apr 2021 02:26:59
User entered '9 Feb 2021'	Tammy Kohn (b) (4)	23 Feb 2021 19:33:38

US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

[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 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	22 Apr 2021 02:26:59
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4)	23 Feb 2021 19:33:38

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User entered 'SICKD28'	System	23 Feb 2021 19:33:38

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00
	(b) (4)	

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:06:37
User entered '9 Feb 2021'	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00



**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:06:37
User entered '14:23'	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User entered '9 Feb 2021 14:23'	System	23 Feb 2021 19:35:00

US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 22:06:37
User entered '177.7' cm	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00
DataPoint set to visible.	(b) (4)	
	System	23 Feb 2021 19:33:38

US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 22:06:37
User entered '202' lb	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00
DataPoint set to visible.	(b) (4)	
	System	23 Feb 2021 19:33:38

US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '37.6' C	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00
	(b) (4)	

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00
	(b) (4)	

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:06:37
User entered empty.	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:06:37
User entered '87'	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00



**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User entered 'bpm'	System	23 Feb 2021 19:35:00

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '14'	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00
	(b) (4)	

US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User entered 'breaths/min'	System	23 Feb 2021 19:35:00

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:06:37
User entered '119'	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00

US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User entered 'mmHg'	System	23 Feb 2021 19:35:00

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:06:37
User entered '79'	Tammy Kohn (b) (4)	23 Feb 2021 19:35:00

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User entered 'mmHg'	System	23 Feb 2021 19:35:00

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38



**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:06:21
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 19:35:28

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '9 Feb 2021'	Tammy Kohn (b) (4)	23 Feb 2021 19:35:28
	(b) (4)	

US3402153

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:42:09

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:12
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 19:35:39

**US3402153**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:48:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:27:12
User entered '9 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 19:35:39

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:26:53
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '9 Mar 2021'	Traci Hull (b) (4)	09 Mar 2021 21:26:53
	(b) (4)	

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	09 Mar 2021 21:26:53
	(b) (4)	



**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'UNBLND_DECIDE'	System	09 Mar 2021 21:26:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:42:09

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '06 Jan 2021'	Traci Hull (b) (4)	09 Mar 2021 21:27:27
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:42:09**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	09 Mar 2021 21:27:27
	(b) (4)	

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:42:09

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:27:27
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:42:09

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Traci Hull (b) (4)	09 Mar 2021 21:27:27
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:42:09

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '09 Mar 2021'	Traci Hull (b) (4)	09 Mar 2021 21:27:27
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:42:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	09 Mar 2021 21:27:27
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:42:09

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	09 Mar 2021 21:27:27
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:42:09

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	09 Mar 2021 21:27:27
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:42:09

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:27:27
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:42:09**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'I'	System	09 Mar 2021 21:27:27

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'I'	System	09 Mar 2021 21:27:27

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered missing code ND - Not Done.	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered missing code ND - Not Done.	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:42:09**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered empty.	System	09 Mar 2021 21:29:39
DataPoint set to visible.	System	09 Mar 2021 21:27:27

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered missing code ND - Not Done.	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered missing code ND - Not Done.	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:42:09**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered empty.	System	09 Mar 2021 21:29:39
DataPoint set to visible.	System	09 Mar 2021 21:27:27

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '9 Mar 2021'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '15:36'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered '9 Mar 2021 15:36'	System	09 Mar 2021 21:29:39

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '36.9' C	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Oral (Oral)'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '101'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'bpm'	System	09 Mar 2021 21:29:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '18'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'breaths/min'	System	09 Mar 2021 21:29:39

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '124'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'mmHg'	System	09 Mar 2021 21:29:39



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '72'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'mmHg'	System	09 Mar 2021 21:29:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered missing code ND - Not Done.	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered missing code ND - Not Done.	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:42:09**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered empty.	System	09 Mar 2021 21:29:39
DataPoint set to visible.	System	09 Mar 2021 21:27:27

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '9 Mar 2021'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	



US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '16:30'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered '9 Mar 2021 16:30'	System	09 Mar 2021 21:29:39

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '36.8' C	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Oral (Oral)'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '100'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'bpm'	System	09 Mar 2021 21:29:39

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '18'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'breaths/min'	System	09 Mar 2021 21:29:39

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '133'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'mmHg'	System	09 Mar 2021 21:29:39

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '73'	Traci Hull (b) (4)	09 Mar 2021 21:29:39
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'mmHg'	System	09 Mar 2021 21:29:39

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:29:45
	(b) (4)	

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '9 Mar 2021'	Traci Hull (b) (4)	09 Mar 2021 21:29:45
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:30:07
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	09 Mar 2021 21:30:07
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

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)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	09 Mar 2021 21:30:07
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'mRNA-1273'	System	09 Mar 2021 21:30:07
DataPoint set to visible.	System	09 Mar 2021 21:27:27

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '9 Mar 2021'	Traci Hull (b) (4)	09 Mar 2021 21:30:07
	(b) (4)	

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '15:55'	Traci Hull (b) (4)	09 Mar 2021 21:30:07
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered '9 Mar 2021 15:55'	System	09 Mar 2021 21:30:07

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4)	09 Mar 2021 21:30:07
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'ONCE'	System	09 Mar 2021 21:30:07



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 21:30:07

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:27:43
	(b) (4)	

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '9 Mar 2021'	Traci Hull (b) (4)	09 Mar 2021 21:27:43
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '15:17'	Traci Hull (b) (4)	09 Mar 2021 21:27:43
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered '9 Mar 2021 15:17'	System	09 Mar 2021 21:27:43

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:42:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:27:57
	(b) (4)	

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:42:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '9 Mar 2021'	Traci Hull (b) (4)	09 Mar 2021 21:27:57
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:42:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '15:12'	Traci Hull (b) (4)	09 Mar 2021 21:27:57
	(b) (4)	



**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:42:09**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered '9 Mar 2021 15:12'	System	09 Mar 2021 21:27:57

US3402153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Mar 2021 21:28:02
	(b) (4)	

**US3402153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:33:23
User entered 'I'	System	09 Mar 2021 21:28:02

**US3402153**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Mar 2021 15:52:03

**US3402153**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered '16 Mar 2021'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Mar 2021 15:52:03

**US3402153**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	16 Mar 2021 15:52:03

**US3402153**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	16 Mar 2021 15:52:03
	(b) (4)	

**US3402153**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Mar 2021 15:52:07



**US3402153**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:01
User entered 'I'	System	16 Mar 2021 15:52:07

**US3402153**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:01
User entered '1'	System	16 Mar 2021 15:52:07
DataPoint set to visible.	System	16 Mar 2021 15:52:07

**US3402153**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 20:25:31
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '5 Apr 2021'	Tammy Kohn (b) (4)	05 Apr 2021 20:25:31
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4)	05 Apr 2021 20:25:31
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	05 Apr 2021 20:25:31

US3402153

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	



**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '5 Apr 2021'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '14:54'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 14:54'	System	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '36.3' C	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '96'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 20:28:23



**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '16'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '132'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '84'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	



**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '5 Apr 2021'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '15:46'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 15:46'	System	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '36.8' C	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '86'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 20:28:23



**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '16'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '138'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '84'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:23
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:28:23

**US3402153**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:43
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '5 Apr 2021'	Tammy Kohn (b) (4)	05 Apr 2021 20:28:43
	(b) (4)	



**US3402153**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 20:29:22
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 20:29:22
	(b) (4)	

US3402153

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 20:29:22
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	05 Apr 2021 20:29:22
DataPoint set to visible.	System	16 Mar 2021 15:52:07

US3402153

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:09

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '5 Apr 2021'	Tammy Kohn (b) (4)	05 Apr 2021 20:29:22
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '15:15'	Tammy Kohn (b) (4)	05 Apr 2021 20:29:22
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 15:15'	System	05 Apr 2021 20:29:22

**US3402153**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Tammy Kohn (b) (4)	05 Apr 2021 20:29:22
	(b) (4)	



**US3402153**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	05 Apr 2021 20:29:22

**US3402153**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:42:09**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Apr 2021 20:29:22

**US3402153**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 20:29:28
	(b) (4)	

**US3402153**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 20:29:28

**US3402153**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	13 Apr 2021 17:04:26
	(b) (4)	

**US3402153**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered '13 Apr 2021'	Traci Hull (b) (4)	13 Apr 2021 17:04:26
	(b) (4)	

**US3402153**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	13 Apr 2021 17:04:26

**US3402153**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:42:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	13 Apr 2021 17:04:26
	(b) (4)	



**US3402153**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	13 Apr 2021 17:04:32
	(b) (4)	

**US3402153**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:42:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 17:04:32

**US3402153**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 May 2021 12:19:02
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered '30 Apr 2021'	Traci Hull (b) (4)	03 May 2021 12:19:02
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	03 May 2021 12:19:02
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:42:09**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	03 May 2021 12:19:02

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	



**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 12:19:21

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 12:19:21

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	



**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 12:19:21

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 12:19:21

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:21
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:42:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 12:19:21

**US3402153**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	03 May 2021 12:19:31
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:42:09**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	03 May 2021 12:19:31
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 May 2021 12:20:17
	(b) (4)	



**US3402153**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered '30 Apr 2021'	Traci Hull (b) (4)	03 May 2021 12:20:17
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
	(b) (4)	
User entered '15:00'	Traci Hull (b) (4)	03 May 2021 12:20:17
	(b) (4)	

**US3402153**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:42:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Apr 2021 15:00'	System	03 May 2021 12:20:17

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:42:09**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:36
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:28:37
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Jennifer Molstead (b) (4)	18 Jan 2021 21:25:35
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	03 Sep 2020 20:12:26
	(b) (4)	

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:26:20
User entered 'USA-US059-2021-mRNA-1273-P301000002'	System	19 Jan 2021 19:24:54
User entered 'New'	(b) (4), (b) (6)	19 Jan 2021 19:24:54

US3402153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
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)	18 Jan 2021 21:30:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 21:30:10
Data point term sent to Coder	System	18 Jan 2021 21:29:10
User entered 'Sars Covid 19'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

US3402153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User closed query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 05:03:37
Query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 17:14:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 17:13:02
User opened query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 15:08:19
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32



**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

US3402153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered '10 Jan 2021'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:28:32

US3402153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
Signature has been broken.	Tammy Kohn (b) (4)	05 Apr 2021 20:30:10
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Apr 2021 20:30:10
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
Signature has been broken.	Tammy Kohn (b) (4)	05 Apr 2021 20:30:10
User entered '28 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Apr 2021 20:30:10
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 20:51:06
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'This event is still ongoing' (Site from Safety).	Tammy Kohn (b) (4)	04 Feb 2021 17:01:17
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)	27 Jan 2021 17:34:50
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:28:32



**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

US3402153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32



**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:09
User closed query ' PER CDM: Response noted, however kindly review and confirm if 'NOT APPLICABLE' should be recorded' (Site from DM). Query '	(b) (4) (b) (4), (b) (6)	01 May 2021 08:16:45
PER CDM: Response noted, however kindly review and confirm if 'NOT APPLICABLE' should be recorded' answered with 'PER QUERY UPDATED ACTION TO NOT APPLICABLE' (Site from DM). DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:14:12
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:14:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Apr 2021 13:14:06
User opened query ' PER CDM: Response noted, however kindly review and confirm if 'NOT APPLICABLE' should be recorded' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 01:36:01
User signature succeeded.	Frank Eder (b) (4) (b) (4)	22 Apr 2021 02:29:00
User entered 'None (NONE)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	14 Mar 2021 14:36:22
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	04 Feb 2021 17:01:47
		18 Jan 2021 21:28:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	18 Jan 2021 21:29:01
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Jan 2021 21:28:32
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered '1' reason for change: Per Query Resolution	(b) (4)	
	Jennifer Molstead (b) (4)	18 Jan 2021 21:29:01
User entered '0'	(b) (4)	
	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User closed query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 05:03:53
Query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, clarify.' answered with 'UPDATED AS SUBJECT HAD A CHEST XRAY DONE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 17:11:09
User entered '1' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 17:11:04
User opened query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:09:05
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:28:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:42:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
Signature has been broken.	Tammy Kohn (b) (4)	05 Apr 2021 20:30:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Apr 2021 20:30:10
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
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)	12 Feb 2021 20:51:10
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'subject is still recovering. ' (Site from Safety).	Tammy Kohn (b) (4)	04 Feb 2021 17:01:36
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)	27 Jan 2021 17:34:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:00
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:36:22
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 21:28:32

**US3402153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 17:13:02
User entered '0'	System	18 Jan 2021 21:28:32

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:42:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:36
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:50:10



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Aug 2020 19:53:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Aug 2020 19:53:04
Data point term sent to Coder User entered 'ATORVASTATIN'	System Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:51:56 01 Aug 2020 19:51:17

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'HYPERLIPIDEMIA'	Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '40'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	03 Aug 2020 20:14:24
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	01 Aug 2020 19:59:37
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	01 Aug 2020 19:51:17
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:51:17
	(b) (4)	

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:51:17

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:51:17



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:51:17

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:51:17

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL, PRODUCTSYNONYM: OMEGA 3 [FISH OIL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 16:14:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:14:13
Data point term sent to Coder	System	01 Aug 2020 19:52:56
User entered 'OMEGA 3 FISH OIL'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:52:03

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:03

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'HYPERLIPIDEMIA'	Tarin Gordon (b) (4)	01 Aug 2020 19:52:03

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '2000'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:03

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:03

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:03



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'twice daily (BID)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:03

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:52:03
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	01 Aug 2020 19:52:03

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:52:03
	(b) (4)	

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	03 Aug 2020 20:14:29
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.'	Tarin Gordon (b) (4)	01 Aug 2020 19:59:32
answered with 'ONGOING' (Site from System).	(b) (4)	
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	01 Aug 2020 19:52:03
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	01 Aug 2020 19:52:03
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	Tarin Gordon (b) (4)	01 Aug 2020 19:52:03

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:03

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:52:03
	(b) (4)	



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:03

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Aug 2020 19:52:03

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:52:03

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:52:03

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Aug 2020 19:53:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Aug 2020 19:53:04
Data point term sent to Coder	System	01 Aug 2020 19:52:56
User entered 'ZOLPIDEM'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:52:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'INSOMNIA'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '5'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	03 Aug 2020 20:14:33
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.'	Tarin Gordon (b) (4)	01 Aug 2020 19:59:28
answered with 'ONGOING' (Site from System).	(b) (4)	
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	01 Aug 2020 19:52:31
User entered 'UN UNK 2018'	Tarin Gordon (b) (4)	01 Aug 2020 19:52:31
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:52:31
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:52:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:52:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:52:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:52:31

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 07:52:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 07:52:10
Data point term sent to Coder	System	01 Aug 2020 19:53:57
User entered 'COLACE (Docusate sodium)'	Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:53:44



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'CONSTIPATION'	Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '50'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:53:44
	(b) (4)	



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	
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.'	(b) (4), (b) (6)	03 Aug 2020 20:14:38
answered with 'ONGOING' (Site from System).		
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).	Tarin Gordon (b) (4)	01 Aug 2020 19:59:22
User entered 'UN UNK 2015'	(b) (4)	
	System	01 Aug 2020 19:53:44
	Tarin Gordon (b) (4)	01 Aug 2020 19:53:44
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:53:44
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:53:44

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:53:44



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 20:49:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	05 Aug 2020 20:49:01
Data point term sent to Coder	System	01 Aug 2020 19:56:00
User entered 'VITAMIN B-12'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'SUPPLEMENT'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '1000'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:08:55
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'UPDATED DATA' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	07 Oct 2020 12:24:46
User entered 'ug (ug)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	07 Oct 2020 12:24:40
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 05:57:08
User entered 'mg (mg)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:55:00

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00
	(b) (4)	



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	03 Aug 2020 20:14:43
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	01 Aug 2020 19:59:18
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	01 Aug 2020 19:55:00
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:00

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:55:00



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:55:00

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:55:00

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	(b) (4) (b) (4) Coder Import (b) (4)	04 Aug 2020 14:17:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:17:07
Data point term sent to Coder	System	01 Aug 2020 19:56:00
User entered 'JARDIANCE'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:55:39

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:39

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'TYPE II DIABETES'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:39

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '10'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:39

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:39

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:55:39
	(b) (4)	



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:39

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:55:39
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:39

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:55:39
	(b) (4)	

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	03 Aug 2020 20:14:47
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	01 Aug 2020 19:59:13
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	01 Aug 2020 19:55:39
User entered '10 Apr 2020'	Tarin Gordon (b) (4)	01 Aug 2020 19:55:39

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:39

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:55:39

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:55:39
	(b) (4)	



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:55:39
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:55:39

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:55:39

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:55:39

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 19:57:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 19:57:05
Data point term sent to Coder	System	01 Aug 2020 19:57:00
User entered 'METFORMIN'	Tarin Gordon (b) (4)	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:56:35
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4)	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '500'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:56:35



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'twice daily (BID)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:56:35

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:56:35
	(b) (4)	

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	03 Aug 2020 20:14:51
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	01 Aug 2020 19:59:08
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	01 Aug 2020 19:56:35
User entered '10 Apr 2020'	Tarin Gordon (b) (4)	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:56:35



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:56:35
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4)	01 Aug 2020 19:56:35
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:56:35

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:56:35

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:09

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: NABUMETONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 13:18:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	03 Aug 2020 13:18:11
Data point term sent to Coder	System	01 Aug 2020 19:58:01
User entered 'NABUMETONE'	Tarin Gordon (b) (4)	01 Aug 2020 19:57:31
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:31:44
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 05:57:34
User entered 'OSTEOARTHRITIS'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '750'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'twice daily (BID)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:57:31
	(b) (4)	



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	03 Aug 2020 20:14:56
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 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	01 Aug 2020 19:59:03
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	01 Aug 2020 19:57:31
User entered 'UN UNK 2008'	Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:57:31

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4)	01 Aug 2020 19:57:31
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:57:31

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:57:31



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: BENZAEPRIIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Aug 2020 20:00:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Aug 2020 20:00:07
Data point term sent to Coder User entered 'BENZAEPRIIL'	System Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:59:01 01 Aug 2020 19:58:07

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:07

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'HYPERTENSION'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:07

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '10'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:07

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:07

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:58:07
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:07

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:58:07
	(b) (4)	



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:07

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:07

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	03 Aug 2020 20:15:01
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.'	Tarin Gordon (b) (4)	01 Aug 2020 19:58:58
answered with 'ONGOING' (Site from System).	(b) (4)	
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	01 Aug 2020 19:58:07
User entered 'UN UNK 2010'	Tarin Gordon (b) (4)	01 Aug 2020 19:58:07
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:07

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:07

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:58:07
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:58:07
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:58:07



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:58:07

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:58:07

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 20:00:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 20:00:07
Data point term sent to Coder User entered 'LORATIDINE'	System Tarin Gordon (b) (4)	01 Aug 2020 19:59:01 01 Aug 2020 19:58:37

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:37

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'ENVIRONMENTAL ALLERGIES'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:37

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '10'	(b) (4) Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 19:58:37

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:37

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:58:37
	(b) (4)	



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	01 Aug 2020 19:58:37

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:58:37
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	01 Aug 2020 19:58:37

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:37

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	03 Aug 2020 20:15:07
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.'	Tarin Gordon (b) (4)	01 Aug 2020 19:58:52
answered with 'ONGOING' (Site from System).	(b) (4)	
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	01 Aug 2020 19:58:37
User entered 'UN UNK 2010'	Tarin Gordon (b) (4)	01 Aug 2020 19:58:37
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:37

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	01 Aug 2020 19:58:37

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	01 Aug 2020 19:58:37
	(b) (4)	



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 19:58:37

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:58:37

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 19:58:37

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 19:58:37

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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)	18 Jan 2021 21:32:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Jan 2021 21:32:10
Data point term sent to Coder	System	18 Jan 2021 21:31:17
User entered 'Tylenol'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Sars Covid-19'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '650'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '10 Jan 2021'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:30:28

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:30:28

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 20:09:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	01 Feb 2021 20:09:30
Data point term sent to Coder	System	01 Feb 2021 20:08:31
User entered 'PREDNISONE'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:05
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'COVID 19'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '40'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '28 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 20:08:05

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Feb 2021 20:08:05



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 07:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 07:54:44
Data point term sent to Coder	System	01 Feb 2021 20:09:37
User entered 'ASA'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:42:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'COVID 19'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '325'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:42:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:42:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:42:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '28 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:08:59

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 20:08:59



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 20:08:59

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Feb 2021 20:08:59

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
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: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 23:51:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 23:51:32
Data point term sent to Coder	System	01 Feb 2021 20:10:39
User entered 'METHYLPREDNISOLONE'	Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'COVID 19'	Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '125'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:42:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:42:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:42:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Intramuscular (INTRAMUSCULAR)'	Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '28 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 20:10:16

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Feb 2021 20:10:16

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:42:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 21:32:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 21:32:31
Data point term sent to Coder	System	01 Feb 2021 20:11:40
User entered 'BENZONATATE'	Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'COVID 19'	Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '200'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13



US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:42:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:42:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13
	(b) (4)	

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'as needed (PRN)'	Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

US3402153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:42:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '28 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered '0'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13



**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:27:19
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 20:11:13

**US3402153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:42:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 20:11:13

US3402153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:42:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:36
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:29:22
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	01 Feb 2021 20:11:31
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	03 Sep 2020 20:12:17
	(b) (4)	

**US3402153**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 22:42:09**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
	(b) (4)	
User entered '28 Jan 2021'	Tammy Kohn (b) (4)	01 Feb 2021 20:12:00
	(b) (4)	



**US3402153**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
	(b) (4)	
User entered 'CHEST XRAY'	Tammy Kohn (b) (4)	01 Feb 2021 20:12:00
	(b) (4)	

**US3402153**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
	(b) (4)	
User entered 'Adverse Event (AE)'	Tammy Kohn (b) (4)	01 Feb 2021 20:12:00
	(b) (4)	

US3402153

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 22:42:09**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:27:50
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	01 Feb 2021 20:12:00
	(b) (4)	

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered		
'USA-US059-2021-MRNA-1273-P301000002'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54



**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Frank'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Eder'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered '1290 Upper Front Street'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Binghamton'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'NY'	System	19 Jan 2021 19:24:54



**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered '13901'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 14:23:09
User entered 'US'	System	19 Jan 2021 19:26:47

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Apr 2021 13:33:07
User entered '2'	System	24 Feb 2021 14:23:24
User entered '1'	System	19 Jan 2021 19:26:47

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'USA-US059-2021-MRNA-1273-P301000002'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54



**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Frank'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Eder'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered '1290 Upper Front Street'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Binghamton'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'NY'	System	19 Jan 2021 19:24:54



**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered '13901'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 14:23:09
User entered 'US'	System	19 Jan 2021 19:26:47

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Apr 2021 13:33:07
User entered '2'	System	24 Feb 2021 14:23:24
User entered '1'	System	19 Jan 2021 19:26:47

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:42:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
User entered '19/Jan/2021 19:26'	System	19 Jan 2021 19:26:47

US3402153

Folder: SAE USA-US059-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:42:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 14:23:09
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 19:26:47

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'USA-US059-2021-MRNA-1273-P301000002'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54



**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Frank'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Eder'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered '1290 Upper Front Street'	System	19 Jan 2021 19:24:54



**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Binghamton'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'NY'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered '13901'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 14:23:09
User entered 'US'	System	19 Jan 2021 19:26:47

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Apr 2021 13:33:07
User entered '2'	System	24 Feb 2021 14:23:24
User entered '1'	System	19 Jan 2021 19:26:47

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:42:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
User entered '24/Feb/2021 09:23'	System	24 Feb 2021 14:23:24

US3402153

Folder: SAE USA-US059-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:42:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 02:28:31
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 14:23:24

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'USA-US059-2021-MRNA-1273-P301000002'	System	19 Jan 2021 19:24:54



**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'No (N)'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Frank'	System	19 Jan 2021 19:24:54



**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Eder'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered '1290 Upper Front Street'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'Binghamton'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered 'NY'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 19:26:39
User entered '13901'	System	19 Jan 2021 19:24:54

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 14:23:09
User entered 'US'	System	19 Jan 2021 19:26:47

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:42:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Apr 2021 13:33:07
User entered '2'	System	24 Feb 2021 14:23:24
User entered '1'	System	19 Jan 2021 19:26:47

**US3402153**

**Folder: SAE USA-US059-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:42:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 02:28:31
User entered '06/Apr/2021 09:33'	System	06 Apr 2021 13:33:07



US3402153

Folder: SAE USA-US059-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:42:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 01:49:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 02:28:31
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 13:33:07